InstantCheck

Real Time ECG Monitor

INSTRUCTION MANUAL

DailyCare BioMedical

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LIMITATIONS AND EXCLUSIONS

This warranty does not cover repairs necessitated by any damage to equipment caused by mishandling, neglect, abuse, customer modification or failure of the user to follow the published operating instructions. Repaired devices are warranted for a period of 30 days and are subject to the limitations and exclusions described in this document. **DailyCare BioMedical Inc. reserves the right to make design changes in its products without incurring the obligation to incorporate these changes in products previously delivered.** This warranty applies unless DailyCare BioMedical Inc. has agreed to and provided a written exception to this policy.

ATTENTION!

DailyCare BioMedical Inc. assumes no responsibility for any personal injuries or damages sustained by or through use of this product.

The InstantCheck

- will NOT tell you if you have heart problems. Only your physician can do that. You should NOT interpret the measurement results yourself.
- is NOT a diagnostic device. It is only an ECG recorder.
- is NOT a substitute for a traditional ECG diagnosis.
- is NOT recommended for users with pacemakers.

What you should NOT do:

- Do NOT operate InstantCheck while using other electrical devices.
- Do NOT connect InstantCheck to the PC via USB cable when acquiring ECG.
- Do NOT use accessories other than those provided by the manufacturer. Do NOT use USB cable other than that supplied by manufacturer.
- Do NOT subject the device to water and liquid spillage. Do NOT clean with alcohol, acetones or any other flammable chemical agents. Do NOT use with any lotions.
- Do NOT place the device and its accessories under direct sunlight and harsh environments.
- Do NOT disassemble InstantCheck. It may cause device malfunction, device failure or damage and you will loose all warranty.

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INTRODUCTION

1.1 What is InstantCheck

InstantCheck is a non-invasive, handheld heart monitoring device. It allows users to measure and record electrical activities of the heart anywhere and anytime. It records and displays real-time electrocardiogram (ECG).

Electrical signals of the heart can be obtained using two methods. The first method is by placing thumbs on InstantCheck's specially designed dry conducting electrodes. The second method is by using external electrode cable and adhesive ECG electrode pads.

InstantCheck records 30 seconds of "Modified ECG signal"[1] for each measurement. After measurement, the device will instantly display the average of 3 parameters on the LCD panel: the average heart rate (HR), ST segment deviation (ST) and QRS interval (QRS). These parameters are not the traditional standard ECG readings, but rather, a "Modified Lead I -ECG"[2].

InstantCheck can transfer all recorded measurements to a personal computer through USB connection for management and analysis of ECG data.

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[1] InstantCheck uses two conducting electrodes to measure cardiac activities, unlike traditional ECG device which requires at least 3 electrodes. ECG measured by InstantCheck is designated as a modified Lead I ECG.

[2] These parameters from InstantCheck are for reference only. For interpretation of the parameters, please consult professional physicians. Additional standard 12 lead ECG test may need to be performed.

1.2 Benefits of InstantCheck

InstantCheck is a recording device used to monitor or spot-check the electrical activities of the heart anytime and anywhere. It is designed to be small, portable and easy to use. With InstantCheck you can:

- The New Vital Sign

  InstantCheck enables qualified medical personnel to quickly spot-check for irregular heart beat during primary assessment.

- Take measurements anytime anywhere

  InstantCheck's compact design allows the user to carry the device anywhere, anytime for periodic monitoring of his/her heart throughout the day.

- Manage ECG recordings over time

  InstantCheck software allows users to manage ECG recording with a time stamped record.

- Patient to Physician

  Data generated by the InstantCheck can be printed, faxed, or emailed using the accompanying software. The InstantCheck also stores up to 100 records for review using the LCD screen.

1.3 ECG Variables

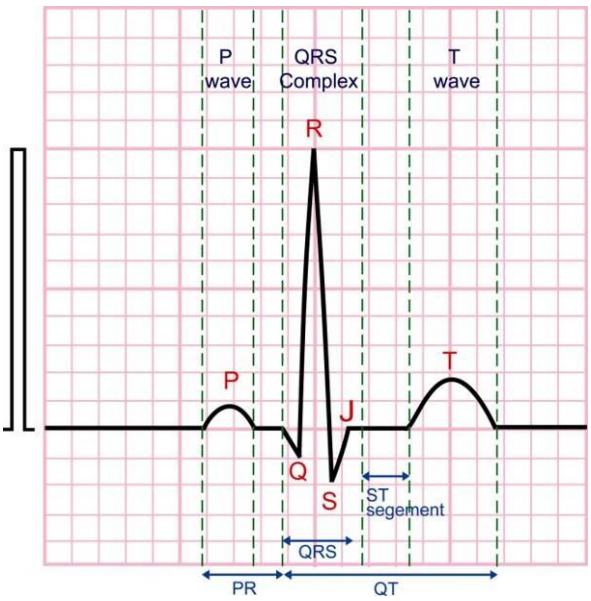


Figure 1. Normal ECG Waveform (Lead I)

Figure 1 is a presentation of a normal ECG waveform from Lead I. InstantCheck uses patented algorithms to identify and compute parameters in the table listed below. Table 1 is a list of ECG parameters measured by InstantCheck.

Table 1 InstantCheck Output Parameters

Parameters	Reference Range
Average Heart Rate (HR)*	60 < HR <100 bpm
ST Segment (ST)*	-2 < ST < +2 mm
QRS Interval (QRS)*	0.08 sec < QRS < 0.12 sec
PR Interval	0.12 ~ 0.20 sec
QT/QTc	0.32 ~ 0.44 sec / 0 .41 ~ 0.44 sec

* The hardware only shows HR, ST and QRS. The PR and QT/QTc will be provided in analysis software (provided) on your computer.

Table 2 InstantCheck Display Messages

Message	Description
1. Regular Heart Rate - Fast Heart Rate - Slow Heart Rate - High ST Value - Low ST Value - High QRS Value	Heart rhythm is REGULAR - If heart rate is too fast (HR > 100 bpm) it will be indicated. - If heart rate is too slow (HR < 60 bpm) it will be indicated. - If ST value is too high (ST > +2 mm), it will be indicated. - If ST value is too low (ST < -2 mm), it will be indicated. - If QRS value is too high (QRS > 0.12 sec), it will be indicated.
2. Irregular Heart Rate	Heart rhythm is IRREGULAR - If this warning appears frequently, regardless if you have any uncomfortable symptoms or not, please consult your physician.
3. Impossible to Analyze (Please measure again.)	Acquired signals CANNOT be analyzed. Please measure again.

ATTENTION:

The parameters and messages provided by the device are for reference ONLY. **If the user feels any discomfort, regardless of the results from the device, please consult an appropriate physician immediately.** Measured data by InstantCheck may be provided to a physician for reference and further analysis.

1.4 Common Causes of Abnormal ECG Tracings

Abnormal ECG tracings may be caused by many different factors, including:

- Coronary artery disease
- Electrolyte imbalances in your blood (such as sodium or potassium)
- Changes in your heart muscle
- Injury from a heart attack
- Healing process after heart surgery

Please consult your physician if you are concerned about your ECG recording and symptoms to get more information about your condition.

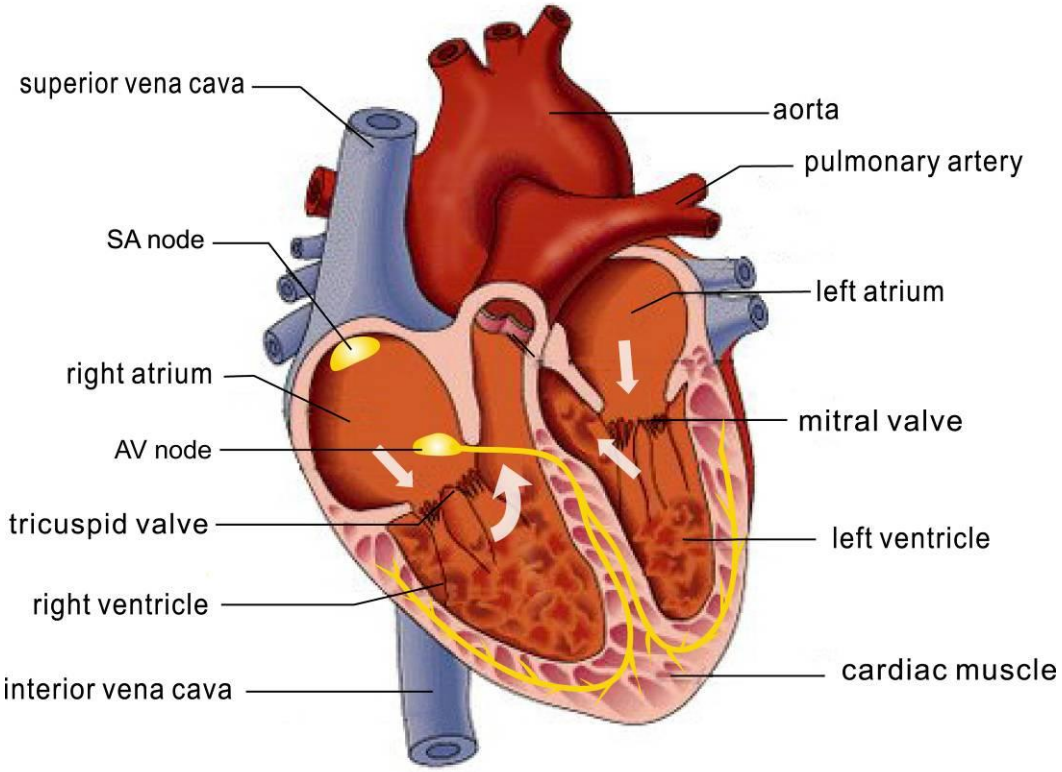
1.5 Basic Function of the Heart

The heart has 4 chambers that act together to pump blood throughout the body. The 2 smaller upper chambers are called atria, and the larger lower chambers are called ventricles. The right atrium receives oxygen-depleted blood coming back from the body via 2 large veins: the superior vena cava and inferior vena cava. The right atrium pumps this blood into the right ventricle, which then pumps the blood into the lungs, which is oxygenated. The blood then comes back into the left atrium, which is then pumped into the left ventricle. The left ventricle then pumps the blood back to the circulatory system via the aorta, the largest artery in the body. The pressure that the left ventricle exerts to keep the blood moving throughout the whole body is the blood pressure.

1.6 Conduction System of the Heart

The chambers of the heart pump with the automatic discharge of electricity from the sinoatrial (SA) node, a group of specialized cells in the right atrium. On average, there are 60 to 100 times discharges per minute. When the SA node discharges, both atria contract, and the electrical impulse is relayed to the atrioventricular (AV) node that is between the 2 ventricles. The electrical wave that is propagated across the AV node causes both ventricles to contract and pump blood. The normal delay

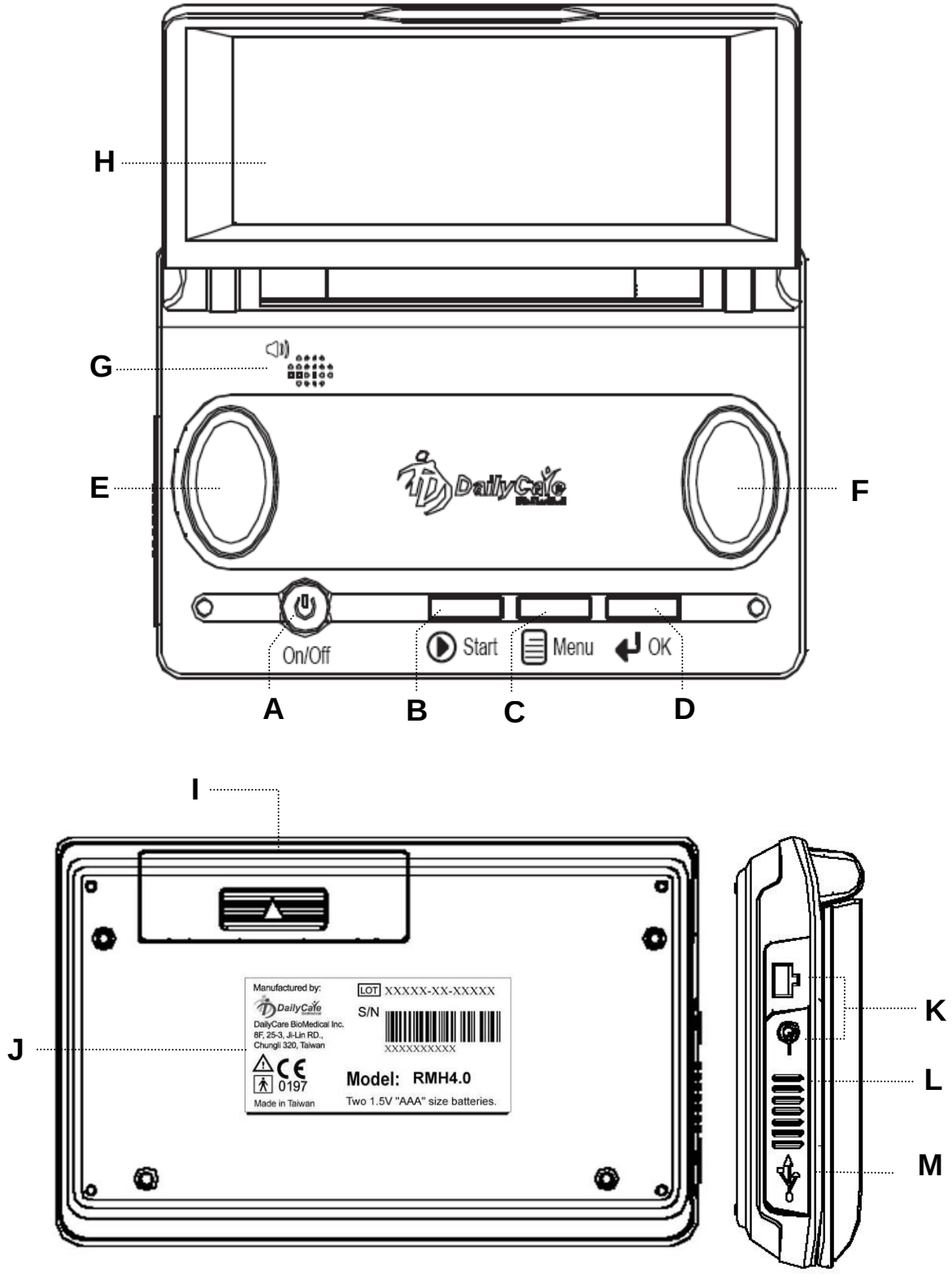
between the atrium and ventricle contractions is 0.12 to 0.20 seconds. By studying the electrical activity that results when heart muscle cells contract, we gain insight to the health and workings of the heart. These electrical activities can be detected, recorded and studied with ECG monitoring device, for example InstantCheck.



PRODUCT DESCRIPTION

2.1 Product Design

2.1.1 Main Unit



Parts Descriptions

Items	Descriptions
A. Power on/off button	Turns the power on and off.
B. Start button	Press to start measuring
C. Menu button	Enter menu mode.
D. Enter/OK button	Press to select. Press to confirm.
E/F. Left and right electrodes	Dry conduction electrodes for thumbs
G. Speaker	Sound
H. LCD panel	Large LCD panel to display parameters and waveform
I. Battery cover	Open cover to insert batteries
J. Product label	Description of device information
K. External electrode cable socket	Insert external electrode cable in this socket
L. Sliding socket cover	Protection mechanism to make sure USB cable and external electrode cable is NOT used at the same time
M. USB socket	Only Insert USB cable provided by manufacturer.

Note: Only use USB cable provided by manufacturer. Other USB cables will cause serious damage to device. Please visit: www.dcbiomed.com to re-order USB cable.

2.1.2 Product Package

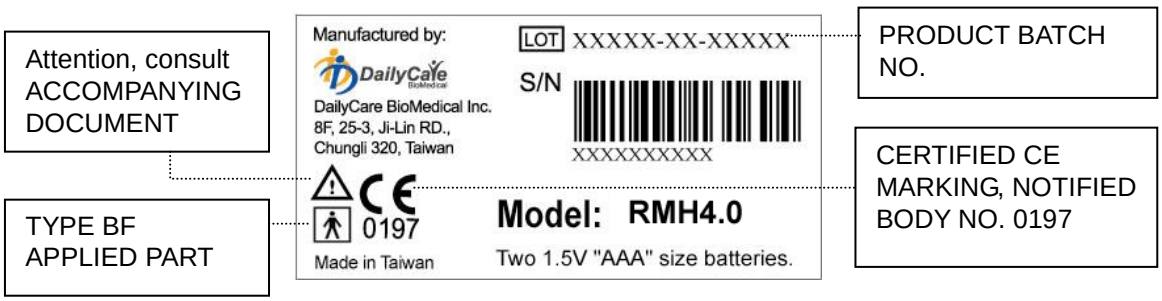
Standard Package:

☑	InstantCheck	x 1
☑	InstantCheck Software CD	x 1
☑	InstantCheck User's Manual	x 1
☑	Carrying Case	x 1
☑	USB Cable	x 1
☑	Auxiliary Electrode Cable	x 1

Not Included:

1) Electrode gel pad. These pads can be purchased at qualified local drug stores.
2) AAA alkaline battery. InstantCheck needs two batteries to operate.

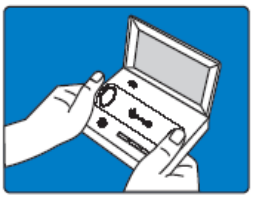
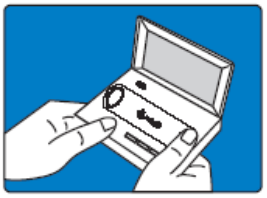
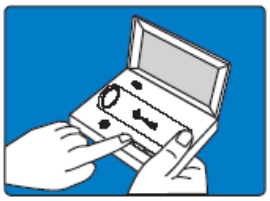
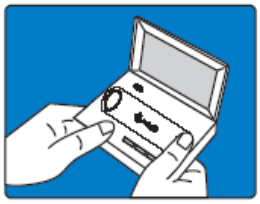
2.1.3 Product Label



InstantCheck is TYPE B EQUIPMENT WITH F-TYPE APPLIED PART IN EN IEC60601-1 STANDARD

2.2 Taking a Measurement

2.2.1 Dry Thumb Conduction Electrodes

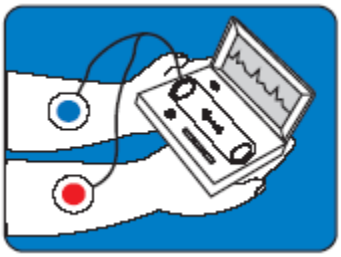
Steps	Descriptions
	Wash and dry your hands before use. Be sure hands are clean of any lotions. Sit down and place your hands comfortably on a table or on your laps.
	Open the lid and press ⏻ once to power on the device.
	Press ⏵ Start to start measuring. Each measurement will take 30 seconds. During measurement, you can stop it anytime by press ↵OK.* Simply press ⏵ again to start the next measurement.
	Place right and left thumbs **GENTLY** on the conduction electrodes. Calm and relax yourself with regular breathing. Do NOT Move and Do NOT Talk during measurement.
	Press ⏻ for 3 seconds to power off the device manually anytime during measurement. Data will NOT be saved. The device will power off automatically if left idle for more than 1 minute.

NOTE: If measurement is stopped in less than 30 seconds, the recorded data is not enough for calculation. The ECG parameters will not be display or recorded. The hardware and software will only show ECG trace measured.

2.2.2 Optional External Electrode Cable

InstantCheck has optional electrode cable as an alternative way for users to take an ECG reading, instead of dry thumb conduction electrode. Please only use one method at a time.

Follow the steps below when using the auxiliary electrodes:

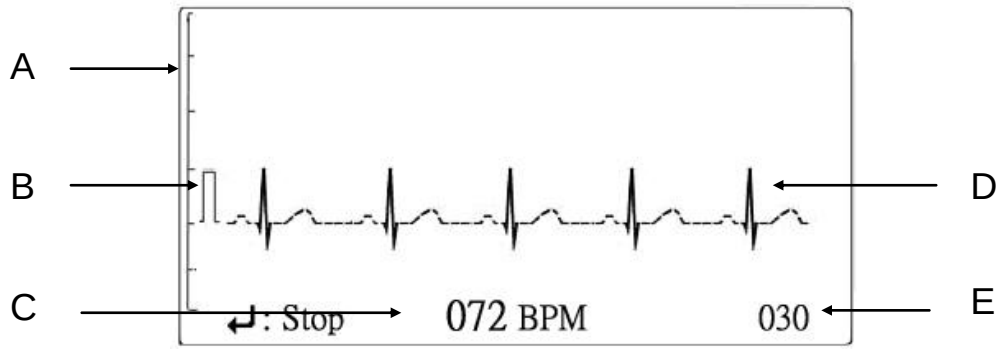
Steps	Descriptions
1	Slide the socket cover to expose the optional electrode cable socket and connect one end of the cable to the device. Connect the split ends of the cable to the adhesive ECG electrode pads. **(Users can buy qualified electrode pads from qualified medical device and pharmacy stores.)**
2	 Place the RED electrode on the right arm and the BLUE electrode on the left arm as shown. Do NOT put your thumbs on the dry conduction electrodes when using this method.
3	Start the measurement by pressing Start.

NOTE: Both auxiliary electrode and USB sockets on the device are to be used only with the standard accessories provided. Warranty will NOT cover damages that result from failure to comply with these instructions. Visit: www.dcbiomed.com to order replacement parts.

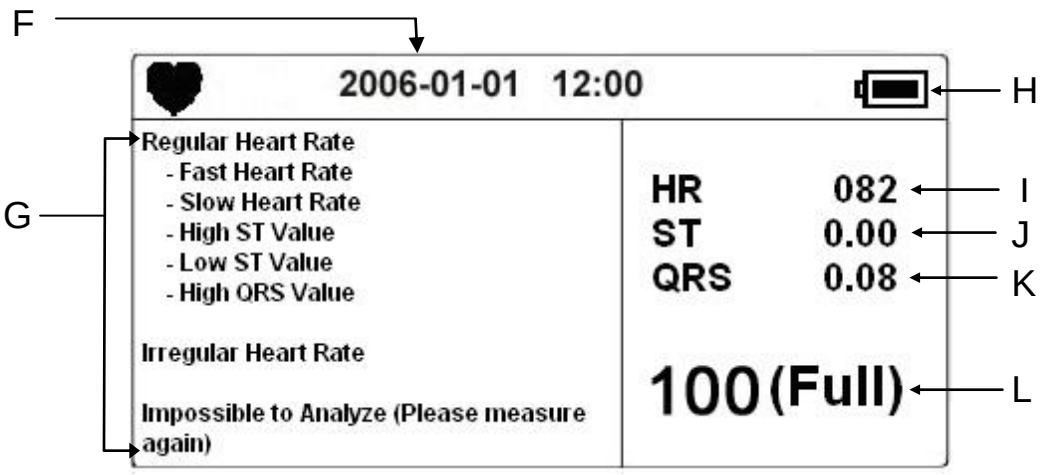
2.3 Display Panel

InstantCheck has a large LCD panel to display operating steps, results of ECG measurements, date/time settings and playback.

2.3.1 LCD Display



LCD Display Panel – During measuring



LCD Display Panel – After measuring

2.3.2 LCD Display Description

#	Item	Descriptions
A	Scale Indicator	ECG scale
B	Amplitude Indicator	Calibration Mark, Unit amplitude (1mV)
C	Heart rate Display	Display Heart rate during measurement
D	ECG trace	ECG waveform display during measuring and review mode
E	Timer	Timer
F	Date/Time	Day/Month/Year Hour/Minute
G	Messages	The messages may include Regular Heart Rate (Fast/Slow Heart Rate, High/Low ST, High QRS), Irregular Heart Rate and Please Measure Again.
H		indicates the battery is normal. indicates the battery is low.
I	HR	Average Heart Rate. Reference range: 60 < HR < 100 bpm
J	ST	ST segment. Reference range: -2 < ST < +2 mm
K	QRS	QRS interval. Reference range: 0.08 < QRS < 0.12 sec
L	Data Stored	Shows how many readings are stored. The device has a looping memory and can store up to 100 readings.

2.4 Menu

Press to power on the device then press to enter Menu mode. In Menu, press menu button to scroll through options. Press OK to enter. Press to start measurement anytime. Below is a list of choices in the menu :

Items	Descriptions
Transmit Data	Transmit data to PC.
Continuous Mode	Special measuring mode: ECG will be continuously displayed on the LCD. The user can manually stop measurement. Only the last 30 seconds of data will be stored.
Review ECG	Select a file to review the ECG parameters and waveform.
System Setting	Three functions: Date & Time*, LCD Brightness, and LCD Contrast can be adjusted.
Erase All Data	Erase all readings stored in memory.
Attention	Attention to using the device.

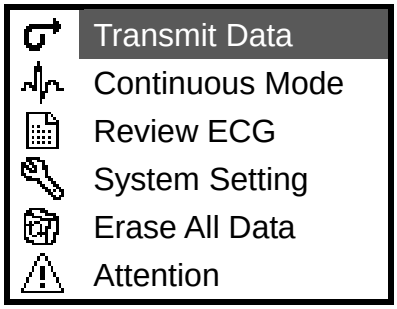
NOTE: Please set the Date & Time before use

2.4.1 Transmit Data

a. Press to enter menu selection when the device is on.

b. Press to send data to PC.

NOTE: Make sure the USB cable is connected to the device and the PC. Make sure the software shows connected.

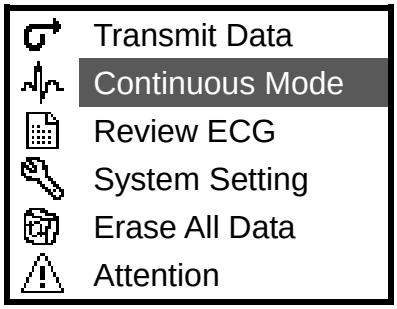


2.4.2 Continuous Mode

This is an alternative recording mode. Selecting this mode will allow you to measure and display your ECG waveform continuously for up to 2 hours. You can choose to stop anytime or manual stop anytime. Only the last 30 seconds will be recorded and stored in memory.

a. Press to enter menu selection when the device is on.

b. Continuous mode will be highlighted.



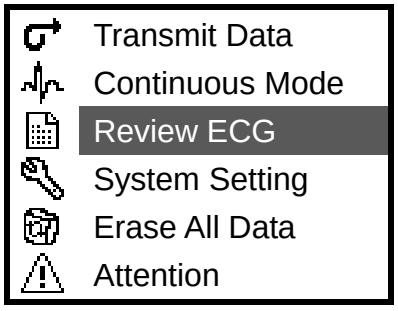
c. Press to start measuring and displaying ECG waveform on LCD.

Press again when you want to manually stop. The device will record the last 30 seconds of data.

2.4.3 Review ECG Data

a. Press ☰ to enter menu selection when the device is on.

b. Press ☰ again until Review ECG is highlighted.

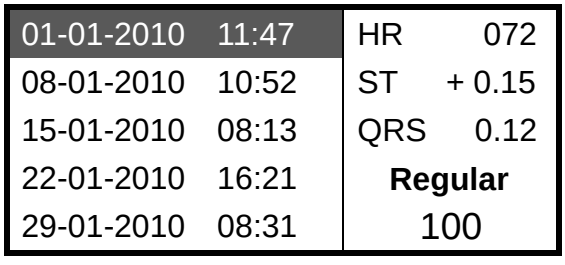


c. Press ↵ to enter Review ECG mode.

d. The newest ECG data file will be placed at the top and highlighted. The highlighted file will display the calculated ECG parameters (HR, ST, QRS) and message will be displayed on the right side of the screen. The file number will be displayed at the bottom right corner. Note: The device can store up to 100 data.

e. Press ☰ to go to next file.

f. Press ↵ to play ECG waveform of highlighted file.



g. To speed up, press and hold ☰. Release ☰ to return to

normal speed.

h. To exit, press ◑.

i. To stop, press ↵. To start again, press ↵.

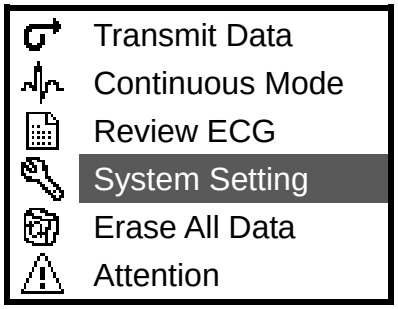
2.4.4 System Setting

Please make sure you have set the right date and time before using the device. Adjust the date and time when needed. The date and time are important information of an ECG data.

a. Press ⏻ to power on the device.

b. Press ☰ to enter menu selection.

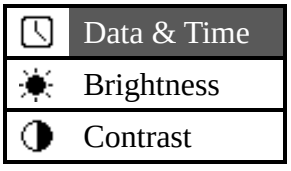
c. Press ☰ again until System setting is highlighted.



d. Press ↵ to enter setting menu selection.

1. Set and Adjust Date and Time:

a. Press ↵ to enter Date & Time adjustment mode.



b. The digit to be changed will be highlighted. Press ◑ to go to next digit to change. Press ↵ to increase the number.

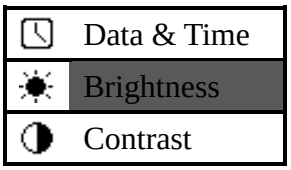
c. When time is set, device will go back to setting menu.

d. Press ◑ to go back to menu.

2. Set and Adjust Backlight Brightness:

The default brightness has been pre-set in the optimal operation for both visual check and battery power consumption. Keep the default brightness is strongly recommended.

a. Press ☰ again until brightness is highlighted.



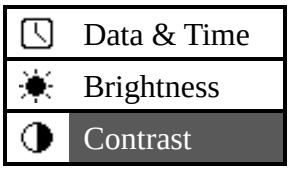
b. The scale will be changed when brightness is changed. Press ◑ to decrease the brightness. Press ↵ to increase the brightness. Press ☰ to go back to setting menu.

c. Press ◑ to go back to menu.

3. Set and Adjust Backlight Contrast

The default contrast has been pre-set in the optimal operation for both visual check and battery power consumption. Keep the default contrast is strongly recommended.

a. Press ☰ again until contrast is highlighted.



b. The scale will be changed when contrast is changed. Press ◑ to decrease the contrast. Press ↵ to increase the contrast. Press ☰ to go back to setting menu.

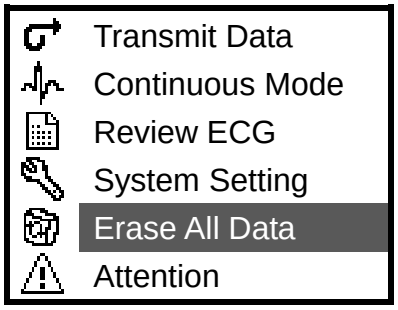
c. Press ◑ to go back to menu.

2.4.5 Erase all ECG Data

You have the option to erase and clear all ECG readings stored. (This will permanently delete all data)

a. Press ☰ to enter menu selection.

b. Press ☰ again until Erase All Data is highlighted.

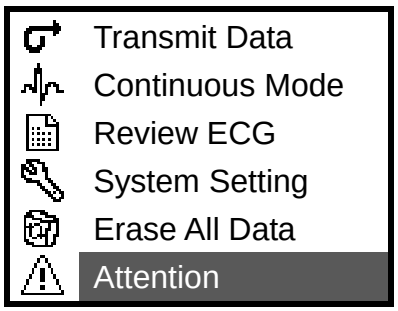


c. Press ↵ to enter. Message will show to confirm if you want to erase all readings. Press ◑ to select Yes or No. Press ↵ to confirm.

2.4.6 Attention

a. Press ☰ to enter menu selection.

d. Press ☰ again until Attention is highlighted.



e. Press ↵ to enter and the following message will show. “The device will not tell if you have heart problems. Only your physician can do that.”

NOTE: This message is to remind that user that if you feel any discomfort, regardless of the results of the measurement by the device, you should consult your physician.

2.5 Product Specifications

Input impedance	> 20 M – Ohm
Input dynamic range	+/- 3 mV
Bandwidth	0.1 – 40 Hz
CMRR (Common Mode Rejection Ratio)	> 95 dB
A/D conversion	12 bit
Sampling Rate	250 samples/sec
Measurement Time	30 seconds
Display	240 X 128 Dot-matrix LCD display
Input	Dry conduction electrodes and/or external auxiliary electrodes
Output	USB interface
Power Supply	1.5V (AAA) X 2
Size	124 x 78 x 22 mm
Weight	150 g excluding batteries
Environmental Conditions:	
Storage temperature	-4°F ~122°F (-20°C~ 50°C)
Operating temperature	50°F ~104°F (10°C ~ 40°C)
Humidity	25% ~ 95%
Measurement Range:	
Average heart rate	45 to 180 bpm
ST segment	-3 to +3 mm
QRS interval	< 0.20 sec

InstantCheck SOFTWARE

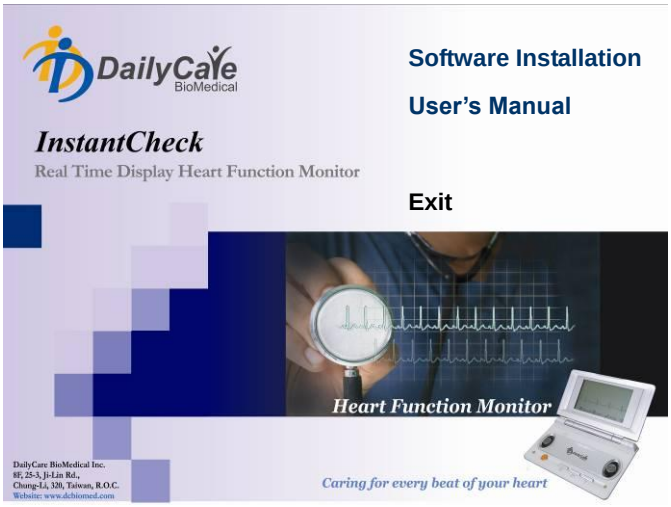
3.1 System Requirements

Operating System: Windows 98/98SE/2000/XP/Vista

Hardware Requirements:

- CPU: Pentium III and above
- Memory: 100MB and above
- Hard disk capacity: 100MB and above
- Data transmission media: Universal Serial Bus (USB)
- Screen resolution: 1024 x 768

3.2 Installation



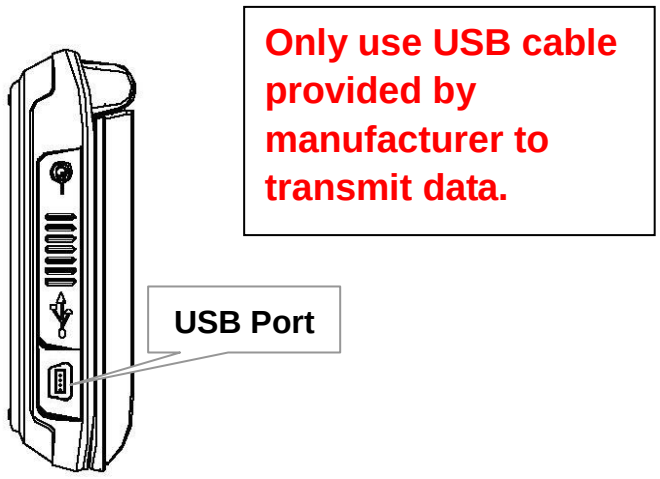
InstantCheck Software Main Page

Insert InstantCheck software CD into the CD-ROM. Select "Software Installation" from the main page and setup will run automatically. If auto-installation does not start, double click on

the “autorun.exe” application file in the CD to install manually. Follow the Setup Wizard instruction on the screen.

3.3 Transmit Data

All data files recorded in InstantCheck can be transferred to PC for analysis through the USB port on the left side of InstantCheck shown as below. Slide the socket cover to expose the USB socket.



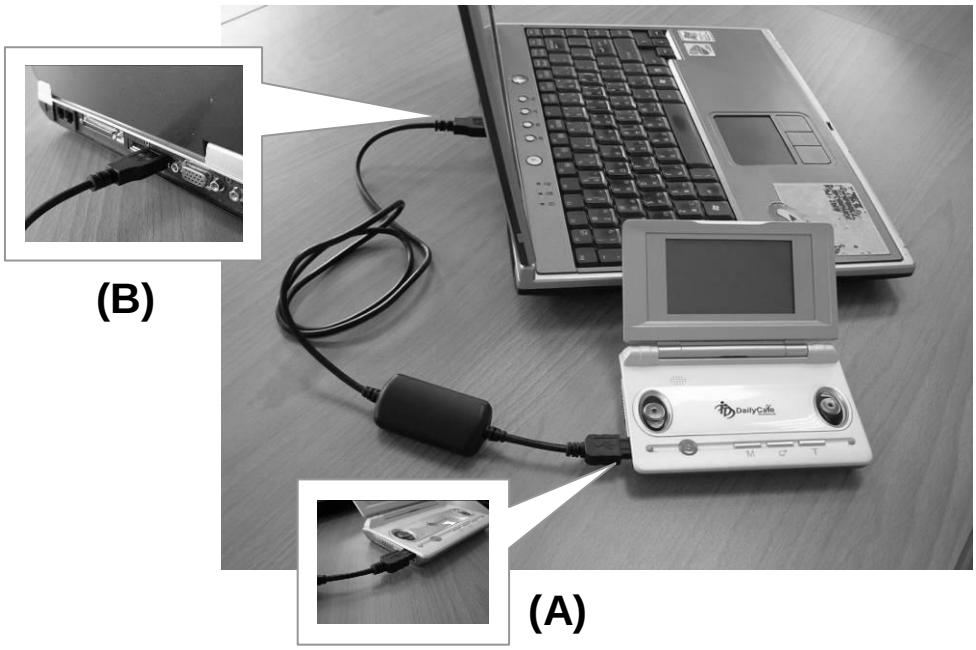
InstantCheck USB port

Steps for file transfer. Please follow the following steps:

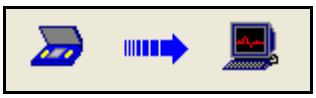
1. Start the InstantCheck software by selecting DailyCare BioMedical Inc. → InstantCheck from the File Menu or by clicking on the on your desktop.
2. A “Disconnected” status will be shown initially on the bottom

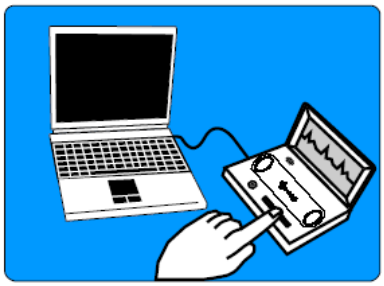
left of the main menu.

Connect one end of the USB cable (small) to the USB socket on the hardware first (A). Then connect the other end of the USB cable to the USB port on the computer (B).



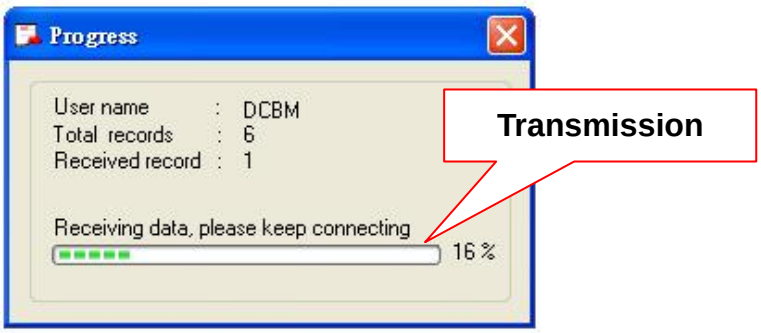
3. When the USB connection detected, it will be indicated on the bottom left corner of the software screen.



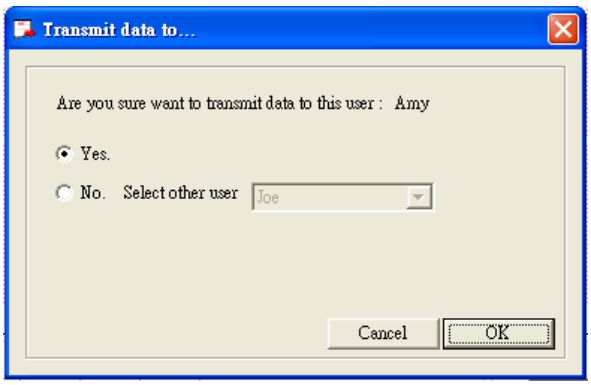


Only use USB cable provided by manufacturer to transmit data.

4. Press ☰ until ↱ Transmit Data is highlighted. Then press ↵ OK to transmit data to PC. Arrow ····➔ will appear on the LCD panel indicating the transferring of data. Data transmission progress window will pop up on the monitor.

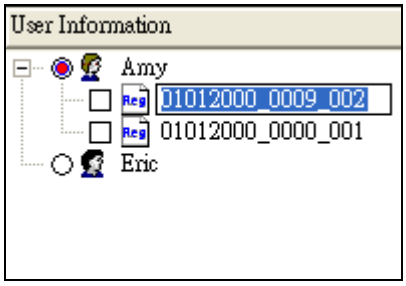


Note: Please confirm/select the right user before the transmitted data save to the PC. The user confirm window as below.



Note: After data files have been successfully transferred to the PC and when you start your next measurement, InstantCheck hardware will erase its memory automatically.

Note: The default file name is the time-stamp of the reading. By clicking the selected file name, the user can change the name.



Note: If ····➔ flashes after pressing ↵ or during file transfer, it means the connection between InstantCheck and the PC has failed. Please close and start the software again, and/or reconnect the USB cable.

3.4 Software Interface

InstantCheck Software User Interface

InstantCheck has a simple analysis interface. This analysis and database management system is divided into four main parts:

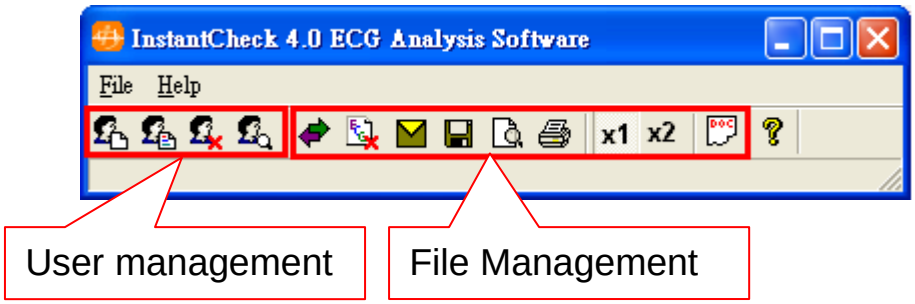
(1) User and file management;

(2) Average ECG parameters display and remarks;

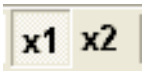
(3) Connection status of ECG to PC;

(4) ECG diagram analysis display (Maximum of 30 seconds).

3.5 User and File Management



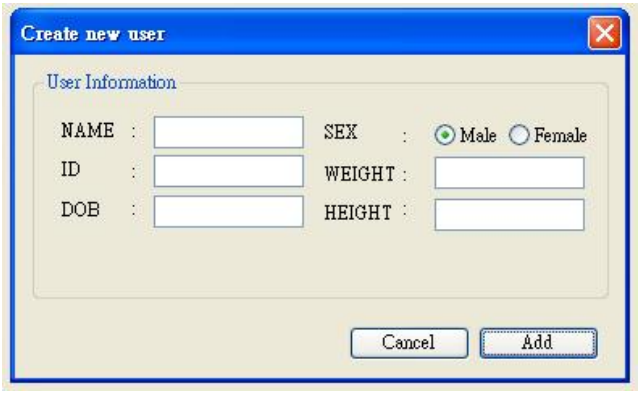
Function Keys	Description
	Add new user
	Display and change user's information
	Delete selected user
	Search for user
	Move ECG file to other user folder
	Delete selected file
	Email ECG data

	Save ECG waveform as graphic file
	Preview ECG report for printing
	Print ECG report
	View between 10mm/mV or 20mm/mV
	Set ECG report header

Detailed descriptions of Function Keys are as follows:

3.5.1 Add New User

1. To add a new user, click on function key. The “Create new user” window will appear as shown below.



2. Enter user information such as name, sex, ID, weight, date of birth (DOB) and height. NOTE: Name has to be keyed to create a new user.

3. Click on Add and a new user will be added to the patient information user list. Name of user must be keyed. Otherwise,

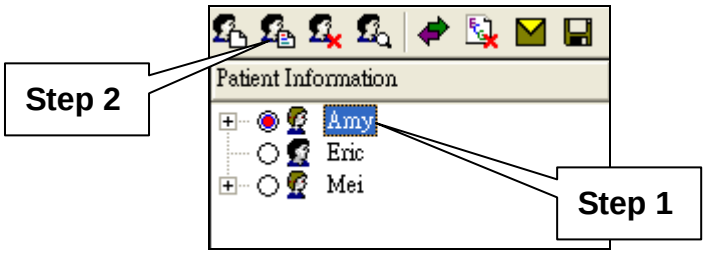
a warning window will appear.

4. Repeat step 1 and 2 to add more new users.

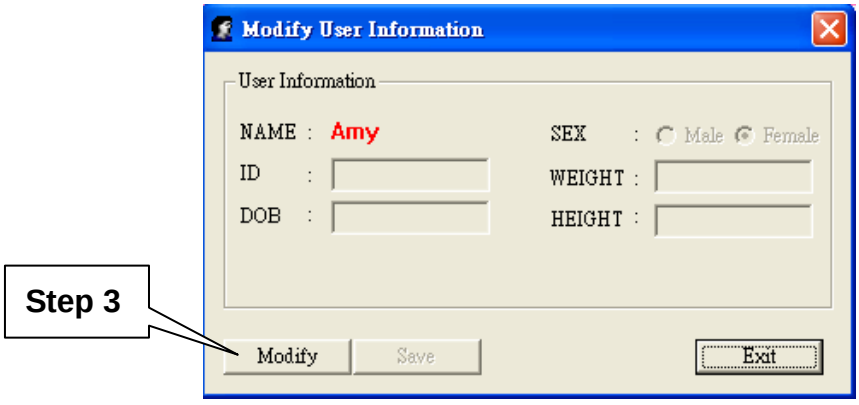
5. Click on [X] to close the user management window.

3.5.2 Display or Change User's Information

1. Select a file/user first.



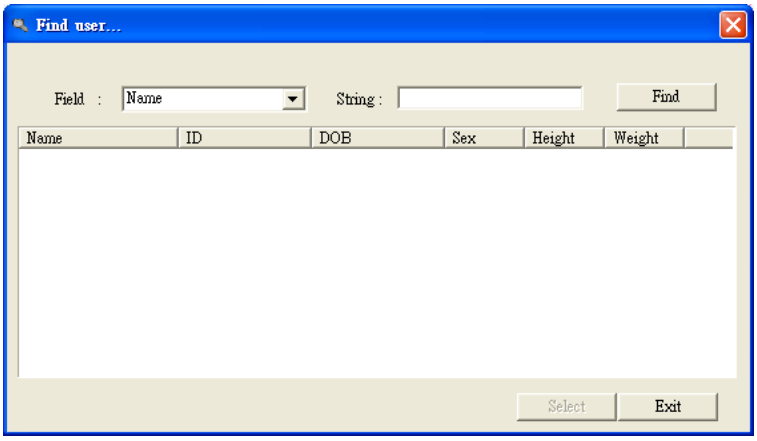
2. Select function key. The user's information will appear as shown below.



3. You can modify the values on the table after click [Modify]. Then click [Save], all the modified values will be saved automatically. Click [Exit], The values will NOT be changed.

3.5.3 Search for User

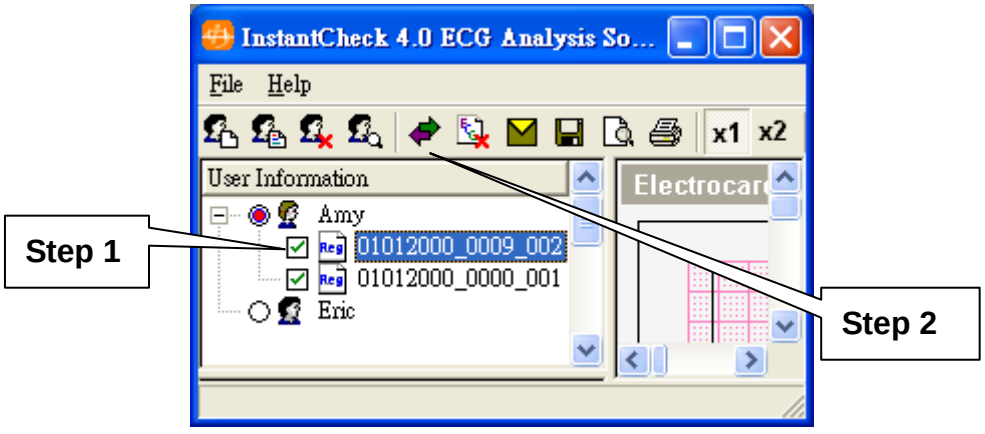
1. Select function key. A window will appear. You can search by “User Name” or by “ID”. Please type in your search characters in the String field.



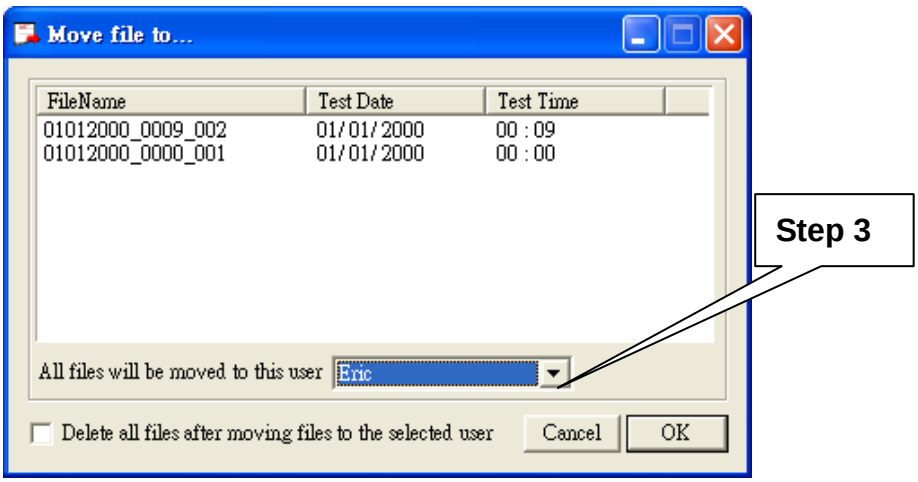
2. Select Find to start finding. If the user is found, the name will be highlighted.

3.5.4 Move ECG File to Other User

1. Select the files first (Multiple files can be selected).

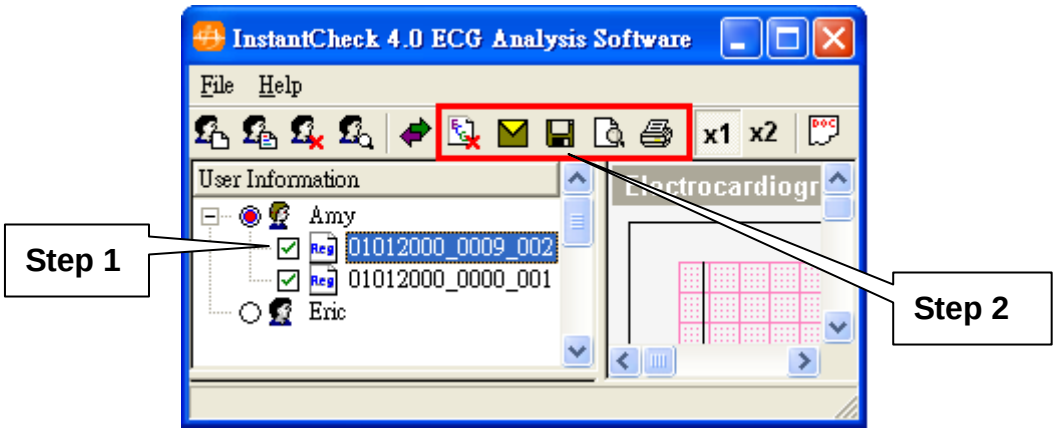


2. Click function key. A window will appear. You can move the selected ECG file to other user.



3.5.5 Delete, E-mail, Save, Preview and Print a File

1. Select the files first (Multiple files can be selected).



2. Click delete, email, save, preview, or print function.

3.5.6 Set Report Header

1. Select function key. The “Report information” window will appear as shown below.

2. Enter header information. Click on Save, and the header information will show on the top of the ECG report.

3.5.7 Review ECG Trace and Parameters

1. Select a user and click on a file.

2. A 30 seconds ECG trace will be shown on the right side of the screen in quadrant 1. (Q1)

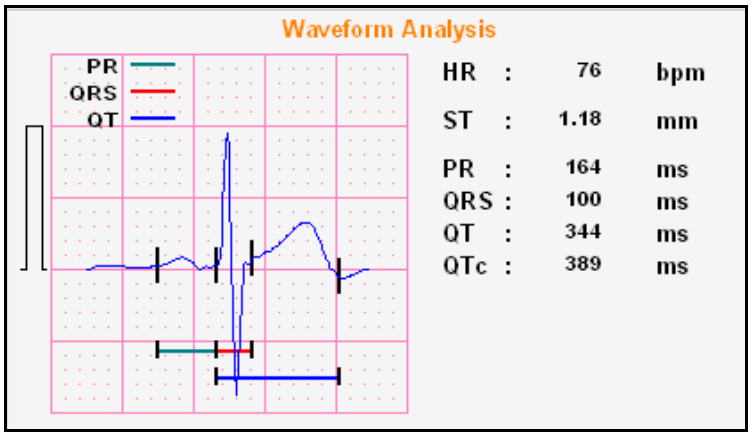
NOTE: If you stop ECG measurement in less than 30 seconds, you will not have the full 30 seconds ECG trace.

3. The average ECG parameters (HR, PR, QRS, QT, QTc, ST) will be displayed in quadrant 2. (Q2)
4. You can also select a particular section of the ECG trace, by clicking left click once to start and left click again to end the section in Q1. The selected part of the trace will turn blue. The average ECG parameters will be displayed in Q2 accordingly.

3.5.8 Redefine ECG Parameters

This section is highly recommended for doctors only. The power of the device lies in the algorithm which identifies and defines P, Q, R, S and T wave intervals to generate the parameters observed on the file. The algorithm is highly precise and accurate which is observed in a correlation study with standard ECG device.

In order to present a flexible format, the software is developed with the ability to redefine the waves. This should only be done by a medical professional who has great experience with ECG analysis and interpretation. Therefore, users are strongly advised against performing the function in this section unless under the guidance of a medical professional.



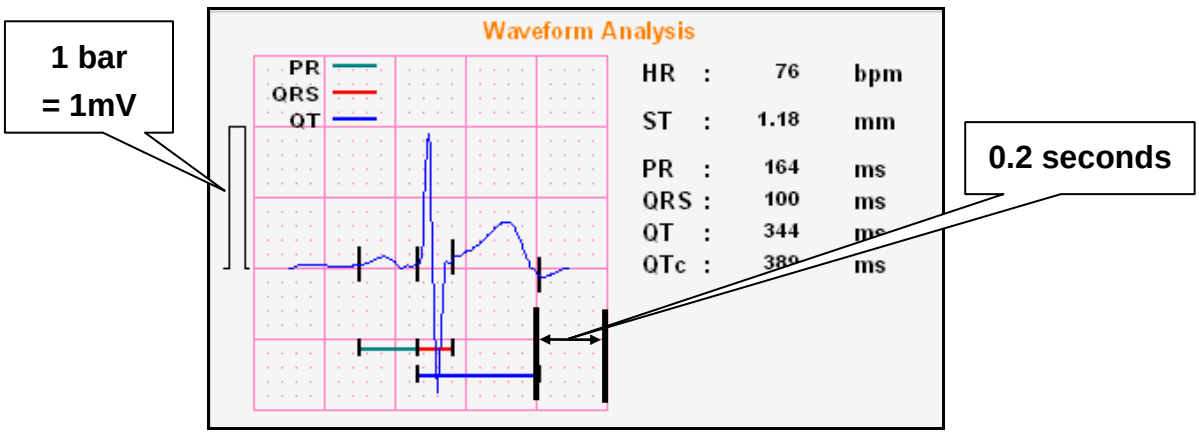
Steps to redefine ECG waves:

1. ECG parameters will be calculated automatically.
2. If you click on the vertical bars on the ECG waveform, it will change to a red bar. Use the left and right arrow key to move it. The software will automatically recalculate the parameters.
3. Left click on the ECG waveform after you have finish adjusting the bar.

3.5.9 Reading the Graph

The Y-axis represents voltage in mV. The bar indicated below represents 1millivolt (mV). This denotes the electrical strength of the signal. Therefore, each big square represent 0.5 mV and each small square represent 0.1mV.

The X-axis represents time in seconds. Each big square represents 0.2 seconds. Therefore, each small square represents 0.04 seconds.



ECG graph

3.5.10 ECG Waves and Parameters

The following is a summary of the ECG wave morphologies and parameters that users can use as a guide to interpret their ECG recordings. For more technical information, please refer to the reference section.

- **P wave:** The P wave results from atria contraction. P wave is generally about 1 box wide or 1 box tall. P wave that exceeds these might indicate atria hypertrophy, i.e., enlargement.
- **PR Interval**: The PR interval is measured from the start of the P wave to the start of Q wave. It represents the duration of **atria depolarization**. Normal duration is from **0.12 to 0.20 seconds.** If the PR interval is greater than 0.20 seconds, then an AV block might be present.
- **QRS Duration**: The QRS duration is measured from the start of Q wave to the end of S wave. It represents the

duration of **ventricle depolarization**. Normal duration is from **0.08 ~ 0.12 seconds**. If duration is longer, it might indicate presence of bundle branch blocks.

- **QT/QT_c**: The QT/QT_c is measured from the start of the Q wave to the end of T wave. QT interval represents the duration of **activation and recovery of the ventricular muscle**. This duration varies inversely with the heart rate. The normal QT_c is approximately **0.41** seconds, it is corrected with the heart rate with the following formula to get QT_C: $QT_C = QT / sqrt (RR)$

  RR is interval between R to R peak.

- **ST Segment**: The ST segment is measured from end of S wave, J point, to the start of T wave. This segment is important in identifying pathology such as myocardial infarction (elevation) and ischemia (depression).

To learn more about the analysis of ECG parameters, please refer to the list of references provided in the Reference Section.

FREQUENTLY ASKED QUESTIONS

Q1:	What is InstantCheck?
A1:	InstantCheck is a handheld ECG monitor. The main function of InstantCheck is to record ECG tracings anywhere and anytime. Users only need to place both thumbs on the electrodes, and their ECG will be recorded. The parameters measured will be displayed on the LCD screen. Together with the software, users can transfer data files to PC for analysis and management of data.
Q2:	Why does “Noise” appear? Why does P wave sometimes disappear during measurement?
A2:	InstantCheck measures the micro-electrical activities emitted by the heart. “Noise” means there is the interference with the recording of these signals due to poor contact between the thumbs and the electrodes, excessive movement of the body, and other strong environment EMI (Electro Magnetic Interference) noise, etc. No P-wave or small Lead I signal: Please try using Lead II by using the external electrode cable and adhesive ECG pad. Please the red end on right arm, and the blue end on left leg.
Q3:	What are some of the factors that may affect the measurement by InstantCheck?
A3:	Besides the factors mentioned in Q2, the followings are some of the factors that may also affect measurements: a. Thumbs may be greasy, which may affect the transmission of signals. Please use clean water to clean the thumbs first. b. Thumbs may be too dry. Do NOT use cream. Please use external auxiliary electrode cable & adhesive ECG electrode pads. c. Contact pressure between the thumbs and the electrodes may be too strong. Please place the thumbs on the electrodes GENTLY. Even when users have followed the regular procedure described in the User’s Manual to operate InstantCheck, the user may still experience a weak signal. Please contact the distributor, retailer, or visit DailyCare BioMedical Inc.’s website:http://www.dcbiomed.com

Q4:	Why do you need to use auxiliary electrode cable? How do you use the optional auxiliary electrodes?
A4:	The auxiliary electrode cable is for users who cannot hold InstantCheck steadily without shaking, or users whose thumbs are too dry, or if the signals are too small using dry electrodes. For detailed instructions, please follow the steps described in P.11 of the User's Manual. Please buy extra adhesive ECG electrode pads from a qualified medical device store.
Q5:	Can InstantCheck be stopped or powered off in the middle of the measurement?
A5:	During the 30 seconds measurement, InstantCheck can be stopped or powered off. The measured data will be saved if you stop in the middle of the measurement. If you power off the device in the middle of the measurement, the data will not be saved.
Q6:	Will static electricity affect the measurement of InstantCheck ?
A6:	InstantCheck is CE certified and has passed electromagnetic interference and compatibility tests. Under normal circumstances, static electricity will not affect the operation of InstantCheck. However, strong EMI (Electromagnetic Interference) may affect the operation of the device.
Q7:	How do you manage ECG signals if multiple people use a single InstantCheck device?
A7:	Data cannot be managed on the InstantCheck device directly. If there is more than one user, please use the software provided for data management.
Q8:	Why does the temperature of InstantCheck rise after the batteries are inserted?
A8:	The rise in temperature is caused by the improper direction (polarities) of the poles of the batteries when inserted. Please remove the batteries quickly and then reinsert the batteries correctly. Please allow the InstantCheck to drop to a normal operating temperature before making any measurements.
Q9:	Can the parameters measured by InstantCheck be used for clinical diagnosis?

A9: The ECG tracings recorded by InstantCheck is not for clinical diagnostic purposes. It is only to be used for physician's reference, and to be used for personal home care health management.

Q10: Why does the data recorded in the InstantCheck disappear after batteries are replaced?

A10: Data will remain in the memory for approximately 2 minutes only during battery replacement. Thus, please replace batteries as quickly as possible to preserve data.

Q11: What is the maximum memory of InstantCheck hardware?

A11: InstantCheck can store up to 100 data files in its memory only. When the 100 files limit is exceeded, InstantCheck has a looping memory and will delete the oldest data and save the newest data. Please try to transfer data files to the PC regularly. It is important to save all ECG data for personal health management.

Q12: How do you transfer InstantCheck 's ECG data files by internet?

A12: ECG report can be saved as JPG file using the software. You can send the report as an attached file to your physician for reference, using your regular email account.

Q13: How do you maintain InstantCheck?

A13: When the dry conduction electrodes on InstantCheck are used regularly, grease and dirt may accumulate, which may affect the recording of signal. Please use a clean wiping cloth to remove grease and dirt. Please Do NOT use any cleaning solutions or organic solvents to prevent damaging the device.

Q14: Can InstantCheck use other external power supply?

A14: NO. InstantCheck is to be operated by two replaceable 1.5V (AAA) alkaline batteries. Please Do NOT use other external power supply which may be hazardous and may damage the system and the device.

Q15: Can InstantCheck use accessories other than the ones provided in the standard package?

A15: All standard package accessories meet special specifications of medical device regulations. Please **Do NOT** use any other accessories other than the ones provided in the standard package to avoid hazards and subsequent damages to the device and to avoid hazards.

Q16: What to do if the parameters measured by InstantCheck Do NOT correspond with the user's condition?

A16: In case of an emergency physical condition, users should contact emergency services immediately, or go report immediately to the hospital. If the measured parameters Do NOT correspond with user's condition, please make sure all standard operating procedures are followed. If not, please contact a physician for further check up.

Q17: Can any other fingers be used beside the thumbs for measurement of ECG?

A17: You may use other fingers other than the thumbs for measurment using InstantCheck. Please make sure you place the fingers gently on the electrodes and Do NOT move and talk during measurement. You may choose to use external electrode cable and ECG pads for better ECG trace measurement.

Q18: Can InstantCheck be used while the user is standing up, sitting down, or lying down? Will the measurements make any difference?

A18: Different body positions may affect the cardiac signals slightly. However, by following the standard operating procedure closely, InstantCheck is able to record ECG signals correctly.

Q19: After exercising, can ECG be measured using InstantCheck? Will the measurement be correct?

A19: Yes, ECG can be recorded after exercise. During measurement, please remain in a stable position to avoid noise interference.

Q20: Can InstantCheck be used during commuting?

A20: During commuting, if user is able to keep a stable position, InstantCheck can be used to measure ECG. The usage of InstantCheck is not recommended during the operation of any vehicle.

Q21: Can conducting gel or other fluids be used when using InstantCheck?

A21: InstantCheck is designed to be operated without any conducting gel or other fluids. Please Do NOT apply any conducting gel or other fluids to avoid damaging the thumb electrodes and the device.

GLOSSARY

Aorta

The main trunk of the systemic arteries, carrying blood from the left side of the heart to the arteries of all limbs and organs except the lungs.

Arrhythmia

Irregularity in the heart rhythm.

Atrioventricular (AV) Node

A small mass of specialized cardiac conducting tissue, located in the wall of the right atrium of the heart, that receives heartbeat impulses from the sinoatrial node and directs them to the walls of the ventricles.

Bundle of His

A slender bundle of modified cardiac conducting tissue that passes from the atrioventricular node in the right atrium to the right and left ventricles by way of the septum and that maintains the normal sequence of the heartbeat by conducting the wave of excitation from the right atrium to the ventricles called also *atrioventricular bundle, His bundle*.

Electrocardiogram

The curve traced by an electrocardiograph.

Electrocardiograph

An instrument used in the detection of heart abnormalities. It measures electrical potentials on the body surface and generates a record of the electrical currents associated with heart muscle activity.

Heart Rate (HR)

The number of heartbeat per unit time, usually in minutes.

Hypertrophy

A non-tumorous enlargement of an organ or a tissue as a result of an increase in the size rather than number of constituent cells.

Inferior Vena Cava

Large vein formed by the union of the two common iliac veins that receives blood from the lower limbs and the pelvic and abdominal viscera and empties into the right atrium of the heart.

Left Atrium

Top left chamber of the heart.

Left Ventricle

Bottom left chamber of the heart.

mm

One mm is one small square on the electrocardiograph.

Myocardial Infarction

Formation of an area of tissue that undergo necrosis as a result of obstruction of local blood supply, as by a thrombus or embolus.

P Wave

Atrial Depolarization (contraction). Normal duration is 0.06 - 0.11 seconds.

Parameters

A distinguishing characteristic or feature.

PR Interval

Atrial and AV node depolarization. Regular duration is 0.12 - 0.20 seconds.

QRS Interval

Ventricular depolarization. Regular duration is no longer than 0.1 seconds.

QT Interval

Ventricular refractory time. Duration varies according to rate, age and sex.

Right Atrium

Top right chamber of the heart.

Right Ventricle

Bottom right chamber of the heart.

Right/Left Bundle Branch

Either of the parts of the bundle of His passing respectively to the right and left ventricles.

Sinoatrial (SA) Node

A small mass of specialized cardiac muscle fibers located in the posterior wall of the right atrium of the heart that acts as a pacemaker by generating at regular intervals the electric impulses of the heartbeat.

ST Segment

ST segment represents the period from the end of ventricular depolarization

to the beginning of ventricular repolarization.

Superior Vena Cava
A large vein formed by the union of the two brachiocephalic veins and the azygos vein that receives blood from the head, neck, upper limbs, and chest, and empties into the right atrium of the heart.
T Wave
Ventricular Repolarization. Usually 0.5mV or less in Lead I, II and III.

REFERENCES

1. American Heart Association www.americanheart.org
2. National Heart, Lung and Blood Institute www.nhlbi.nih.gov
3. ECG Library www.ecglibrary.com
4. eMedicine www.emedicine.com
5. HeartCenterOnline www.heartcenteronline.com
6. Arrhythmia Alliance www.heartrhythmcharity.org.uk

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Website: www.obelis.net

ReadMyHeart

Handheld ECG Monitor

INSTRUCTION MANUAL

DailyCare BioMedical

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DailyCare Biomedical Inc warrants each new device to be free from defects in material and workmanship. This warranty is not transferable. This warranty is effective for a continuous period of one year from initial date of shipment against the original order to the original purchaser. This warranty covers parts and labor costs when, upon examination by the manufacturer, the device is determined to be in fact defective. In order to implement the provisions of warranty repair, the purchaser must notify DailyCare Biomedical Inc concerning suspected defects and then, if so instructed, ship the instrument to the designated facility, correctly packed in an appropriate shipping container, for examination and servicing. www.dcbiomed.com

LIMITATIONS AND EXCLUSIONS

This warranty does not cover repairs necessitated by any damage to equipment caused by mishandling, neglect, abuse, customer modification or failure of the user to follow the published operating instructions. Repaired devices are warranted for a period of 30 days and are subject to the limitations and exclusions described in this document. **DailyCare Biomedical Inc reserves the right to make design changes in its products without incurring the obligation to incorporate these changes in products previously delivered.** This warranty applies unless DailyCare Biomedical Inc has agreed to and provided a written exception to this policy.

ATTENTION!

DailyCare Biomedical Inc assumes no responsibility for any personal injuries or damages sustained by or through use of this product.

ReadMyHeart™

- will NOT tell you if you have heart problems. Only your physician can do that. You should NOT interpret the measurement results yourself.
- is NOT a diagnostic device. It is only an ECG recorder.
- is NOT a substitute for a traditional ECG diagnosis.
- is NOT recommended for users with pacemakers.

What you should not do:

- Do NOT operate ReadMyHeart while using other electrical devices.
- Do NOT connect ReadMyHeart to the PC via USB cable when acquiring ECG.
- Do NOT use accessories other than those provided by the manufacturer. Do NOT use USB cable other than that supplied by manufacturer.
- Do NOT subject the device to water and liquid spillage. Do NOT clean with alcohol, acetones or any other flammable chemical agents. Do NOT use with any lotions.
- Do NOT place the device and its accessories under direct sunlight and harsh environments.
- Do NOT disassemble ReadMyHeart. It may cause device malfunction, device failure or damage and you will loose all warranty.

ATTENTION!

Please use the device properly by following standard operating procedure. (Please refer to Section 2.2 Page 9) Improper use of the device will cause inaccurate representation of measured results. NOISE indicator may appear if the device is not operated correctly. If you readings are NOT within the reference range, multiple readings are recommended.

As a rule, if you are feeling uncomfortable, regardless of the numbers and symbols on the device, please consult your physicians immediately!

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INTRODUCTION

1.1 What is ReadMyHeart

ReadMyHeart is a non-invasive, handheld heart monitoring device. It allows users to measure and record electrical activities of the heart anywhere and anytime. It records and displays real-time electrocardiogram (ECG).

Electrical signals of the heart can be obtained using two methods. The first method is by placing thumbs on ReadMyHeart's specially designed dry conducting electrodes. The second method is by using external electrode cable and adhesive ECG electrode pads.

ReadMyHeart records 25 seconds of "Modified ECG signal"[1] for each measurement. After measurement, the device will instantly display the average of 3 parameters on the LCD panel: the average heart rate (HR), ST segment deviation (ST) and QRS interval (QRS). These parameters are not the traditional standard ECG readings, but rather, a "Modified Lead I -ECG"[2].

ReadMyHeart can transfer all recorded measurements to a personal computer through USB connection for management and analysis of ECG data.

---

[1] ReadMyHeart uses two conducting electrodes to measure cardiac activities, unlike traditional ECG device which requires at least 3 electrodes. ECG measured by ReadMyHeart is designated as a modified Lead I ECG.

[2] These parameters from ReadMyHeart are for reference only. For interpretation of the parameters, please consult professional physicians. Additional standard 12 lead ECG test may need to be performed.

1.2 Benefits of ReadMyHeart

ReadMyHeart is a recording device used to monitor or spot-check the electrical activities of the heart anytime and anywhere. It is designed to be small, portable and easy to use. With ReadMyHeart you can:

- The New Vital Sign

  ReadMyHeart enables qualified medical personnel to quickly spot-check for irregular heart beat during primary assessment.

- Take measurements anytime anywhere

  ReadMyHeart's compact design allows the user to carry the device anywhere, anytime for periodic monitoring of his/her heart throughout the day.

- Manage ECG recordings over time

  ReadMyHeart software allows users to manage ECG recording with a time stamped record.

- Patient to Physician

  Data generated by the ReadMyHeart can be printed, faxed, or emailed using the accompanying software. The ReadMyHeart also stores up to 30 records

1.3 ECG Variables

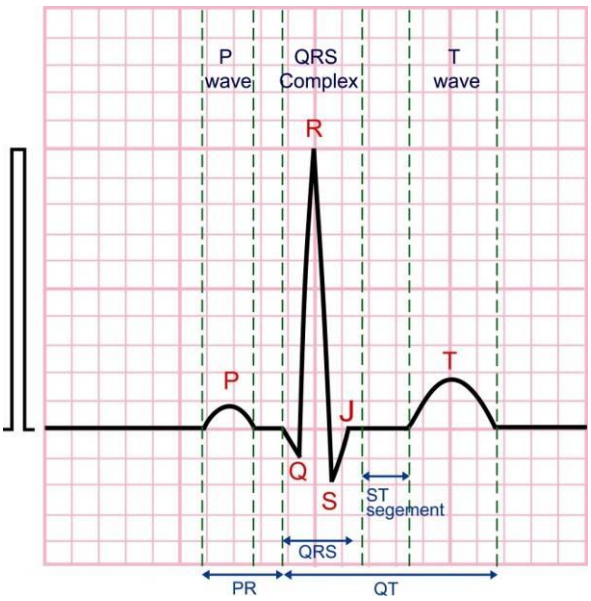


Figure 1. Normal ECG Waveform (Lead I)

Figure 1 is a presentation of a normal ECG waveform from Lead I. ReadMyHeart uses patented algorithms to identify and compute parameters in the table listed below. Table 1 is a list of ECG parameters measured by ReadMyHeart.

Table 1 ReadMyHeart Output Parameters

Parameters	Reference Range
Average Heart Rate (HR)*	60 < HR <100 bpm
ST Segment (ST)*	-2 < ST < +2 mm
QRS Interval (QRS)*	0.08 sec < QRS < 0.12 sec
PR Interval	0.12 ~ 0.20 sec
QT/QTc	0.32 ~ 0.44 sec / 0 .41 ~ 0.44 sec

* The hardware only shows HR, ST and QRS. The PR and QT/QTc will be provided in analysis software (provided) on your computer.

1.4 Common Causes of Abnormal ECG Tracings

Abnormal ECG tracings may be caused by many different factors, including:

- Coronary artery disease
- Electrolyte imbalances in your blood (such as sodium or potassium)
- Changes in your heart muscle
- Injury from a heart attack
- Healing process after heart surgery

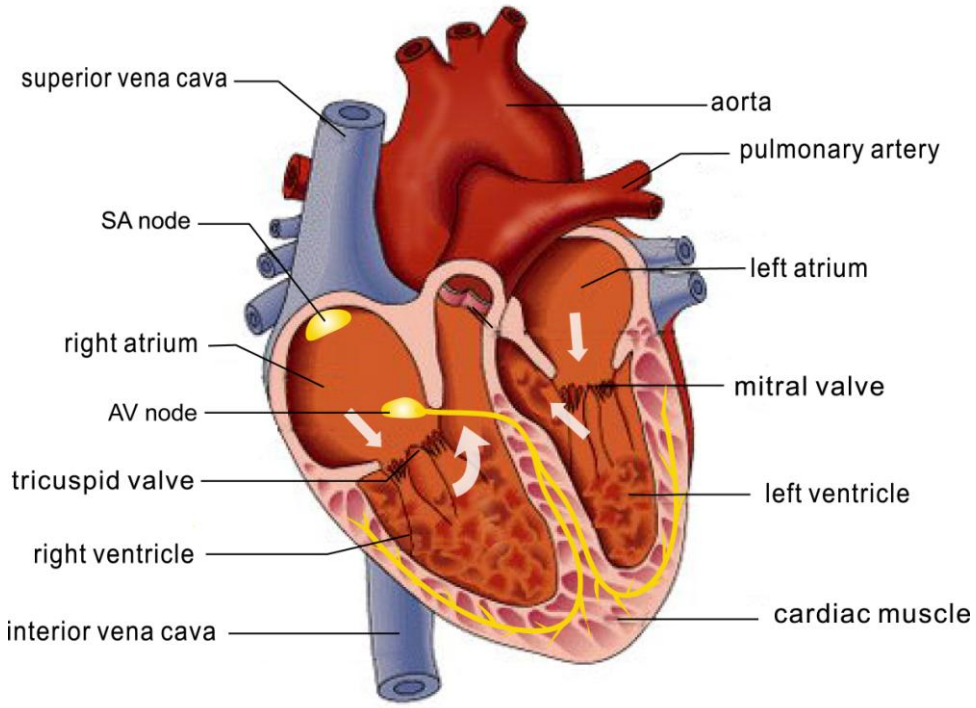
Please consult your physician if you are concerned about your ECG recording and symptoms to get more information about your condition.

1.5 Basic Function of the Heart

The heart has 4 chambers that act together to pump blood throughout the body. The 2 smaller upper chambers are called atria, and the larger lower chambers are called ventricles. The right atrium receives oxygen-depleted blood coming back from the body via 2 large veins: the superior vena cava and inferior vena cava. The right atrium pumps this blood into the right ventricle, which then pumps the blood into the lungs, which is oxygenated. The blood then comes back into the left atrium, which is then pumped into the left ventricle. The left ventricle then pumps the blood back to the circulatory system via the aorta, the largest artery in the body. The pressure that the left ventricle exerts to keep the blood moving throughout the whole body is the blood pressure.

1.6 Conduction System of the Heart

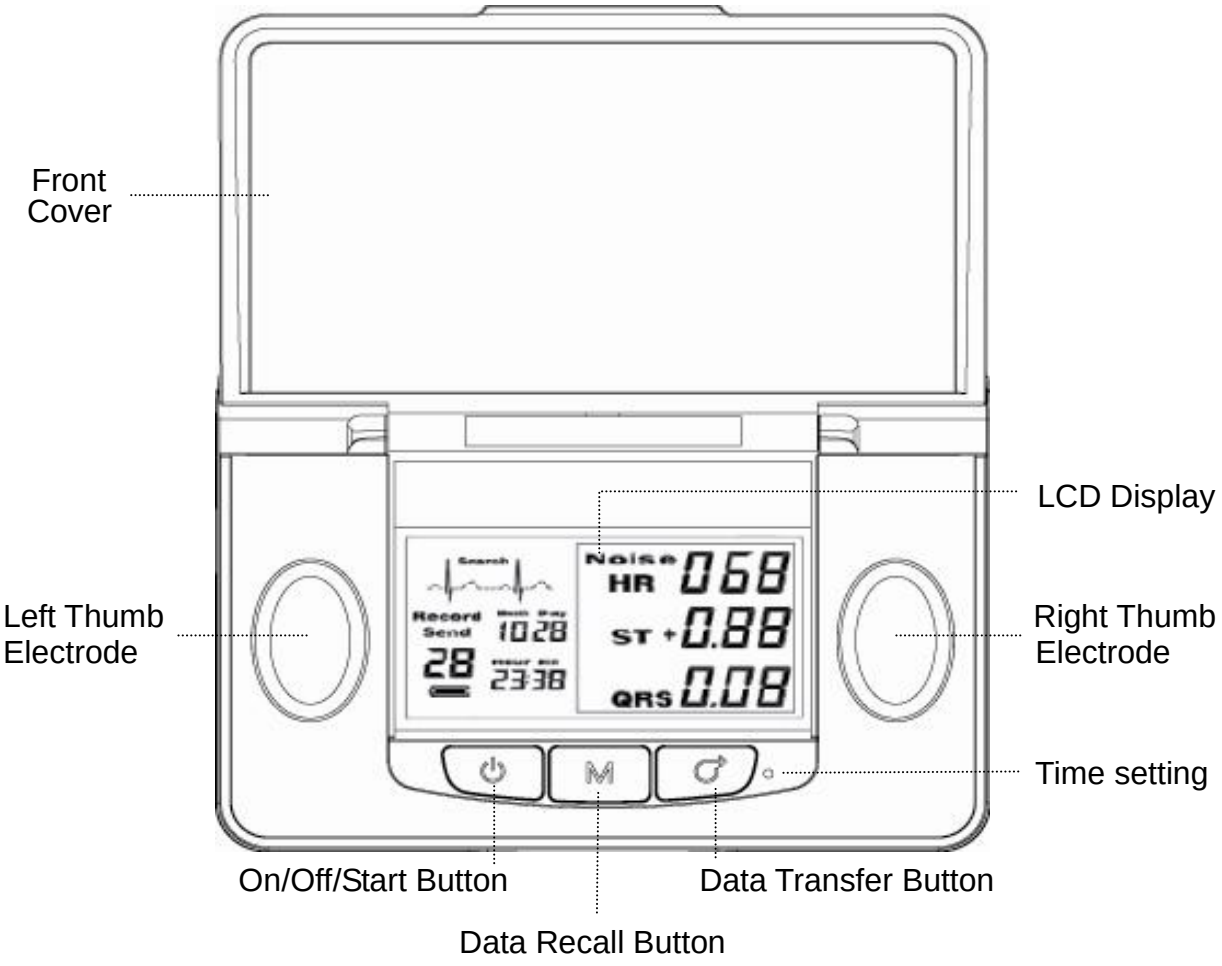
The chambers of the heart pump with the automatic discharge of electricity from the sinoatrial (SA) node, a group of specialized cells in the right atrium. On average, there are 60 to 100 times discharges per minute. When the SA node discharges, both atria contract, and the electrical impulse is relayed to the atrioventricular (AV) node that is between the 2 ventricles. The electrical wave that is propagated across the AV node causes both ventricles to contract and pump blood. The normal delay between the atrium and ventricle contractions is 0.12 to 0.20 seconds. By studying the electrical activity that results when heart muscle cells contract, we gain insight to the health and workings of the heart. These electrical activities can be detected, recorded and studied with ECG monitoring device, for example ReadMyHeart.

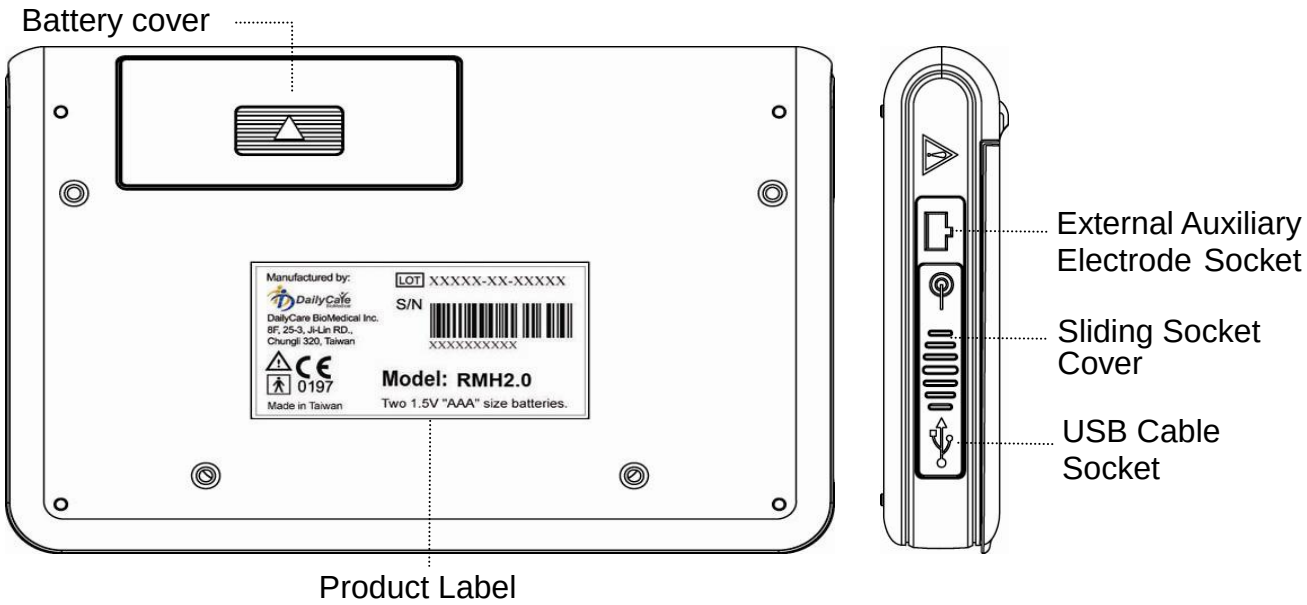


PRODUCT DESCRIPTION

2.1 Product Design

2.1.1 Main Unit





2.1.2 Control Buttons

Control Button Descriptions

Buttons	Descriptions
(Button 1)	**On / Off / Start Button** ~Press once to power on and start measurement. ~Hold for 3 seconds to power off. ~After measuring, press again to start another measurement.
(Button 2)	**Data Recall button / Data Clearance** ~Press once to enter data recall mode. The latest data recorded will be displayed. ~Press again to recall other recorded data, starting from the first. ~Hold for 3 seconds, or press any other button, to leave data recall mode. ~Hold Ⓜ and ☞ together for 3 seconds to manually clear all stored data.
(Button 3)	**Data Transfer Button / Data Clearance** ~Connect ReadMyHeart to PC with USB cable and press once to start transferring of stored data. ~Hold Ⓜ and ☞ together for 3 seconds to manually clear all stored data.
(Hidden Button)	**Time Setting** ~When the device is on, press once to set the right time. ~Press Button 2 Ⓜ to select month/date/time. ~Press Button 3 ☞ to adjust value.

Note: Only use USB cable provided by manufacturer. Other USB cables will cause serious damage to device. Please visit: www.InstantCheck.com to re-order USB cable.

2.1.3 Product Package

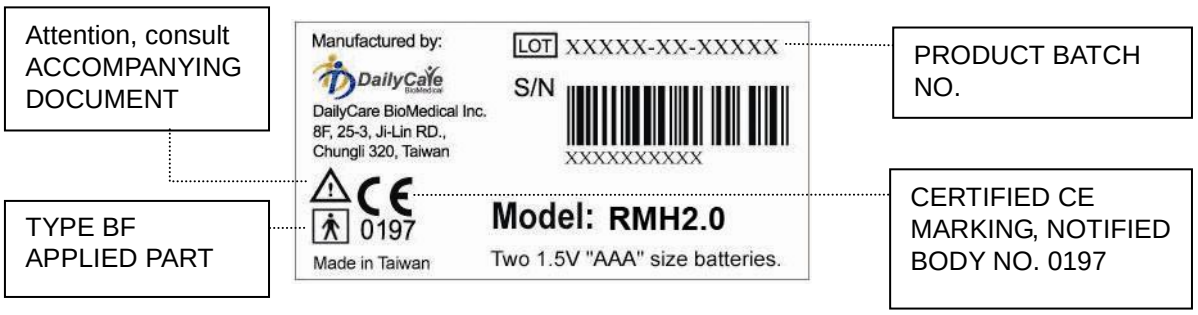
Standard Package:

☑	ReadMyHeart device	x 1
☑	ReadMyHeart Software CD	x 1
☑	ReadMyHeart User's Manual	x 1
☑	Carrying Case	x 1
☑	USB Cable	x 1
☑	Auxiliary Electrode Cable	x 1

Not Included:

1) Electrode gel pad. These pads can be purchased at local drug stores.
2) AAA alkaline battery. ReadMyHeart needs two to operate.

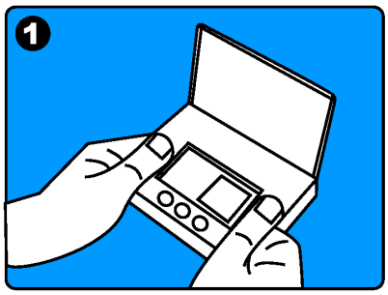
2.1.4 Product Label



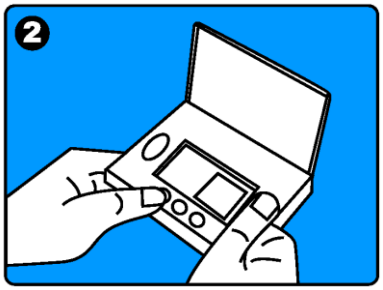
ReadMyHeart is TYPE B EQUIPMENT WITH F-TYPE APPLIED PART IN EN IEC60601-1 STANDARD

2.2 Taking a Measurement

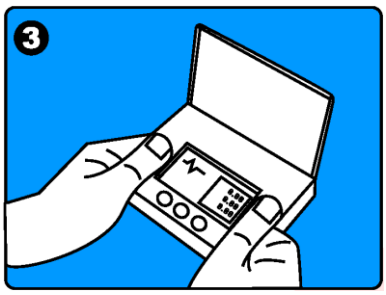
2.2.1 Dry Thumb Conduction Electrodes



Open the cover of ReadMyHeart.



Press ⏻ once to start measuring. (Allow 30 memories)



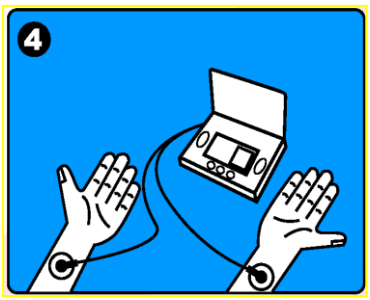
LCD screen will display the parameters after measurement.

Steps	Descriptions
1	**Wash and dry** your hands before use.
2	**Sit down** and place your hands comfortably on a table or on your laps. Hold ReadMyHeart in your hands steadily. Calm and relax yourself with regular breathing.
3	**Press ⏻ once** and **place right and left thumbs gently on the conduction electrodes** to start measurement. - During measurement, a timer will be displayed at the right bottom corner of LCD screen. - During the 25 seconds of measurement, **avoid talking and keep a steady but gentle contact** of the thumbs to the conduction electrodes. - ReadMyHeart can store up to a maximum of 30 data files. The device will stop recording. If you want to do the next measurement, you need to transfer data to PC, or erase the memory. Record number will start to flash at 26th data files to remind you that memory is almost full. - Three parameters of the measured results will be displayed on the LCD screen. To start another measurement, simply press ⏻ again. **Please note that ReadMyHeart cannot be powered off during recording.**

4	**Hold ⏻ for 3 seconds to power off the device**. ReadMyHeart will be powered off automatically if left idle for more than 2 minutes to save power.

2.2.2 Optional External Electrode Cable

ReadMyHeart has optional auxiliary electrodes as an alternative way for users to take ECG readings. Please follow the steps below when using the auxiliary electrodes:

Steps	Descriptions
1	Place the sticky electrode pad (not included) on the middle of the inner forearms. **(Users can buy qualified electrode pads from any medical device stores.)**
2	Slide the socket cover to expose the optional electrode socket, and connect the cable to ReadMyHeart accordingly. Please connect the RED electrode on the right arm and the BLUE electrode on the left arm as shown in figure on the right. 
3	Start the measurement as described above. (Section 2.2.1)

NOTE: Both auxiliary electrode and USB sockets on the device are to be used only with the standard accessories provided. Warranty will NOT cover damages that result from failure to comply with these instructions.

2.3 Display Panel

2.3.1 LCD Display

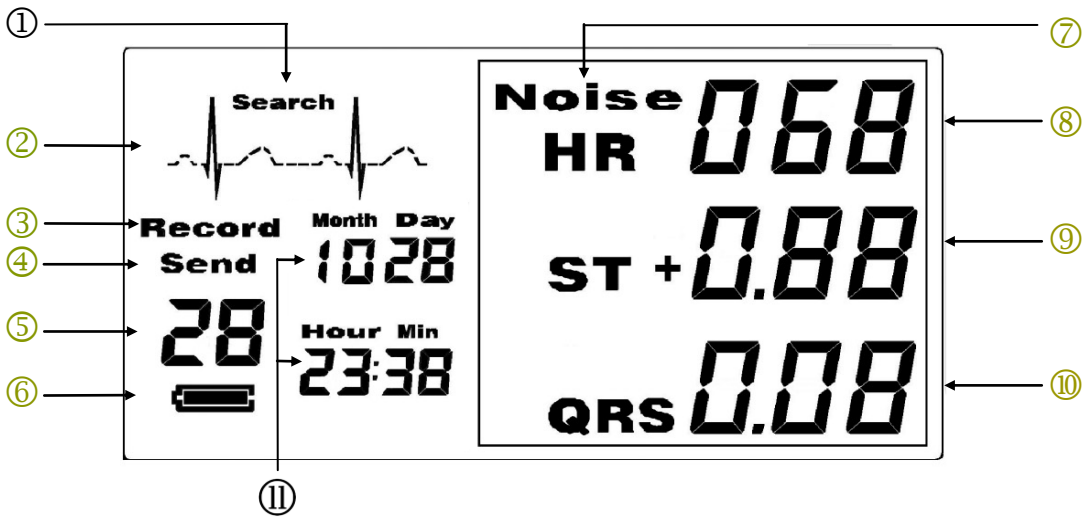


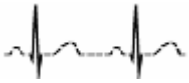
Figure 2. LCD Display Panel

Reference Range of Measured Results

	Reference Range	Warning Sign
HR	60 < HR＜100 bpm	**Flash**
ST	-2 < ST＜+2 mm	**Flash**
QRS	0.08 < QRS＜0.12 sec	**Flash**

Attention: The information above is for reference ONLY. If the measured parameters fall within the reference range and user feels any discomfort, user should contact a physician. Measured data by RMH may be provided to a physician for reference, monitoring, or further analysis.

2.3.2 LCD Display Description

#	Item	Descriptions
①	**Search**	Displays when ReadMyHeart is searching for signals. (Takes around 3~5 seconds)
②		Flashes when measurement is in progress. Flashing stops when measurement is completed.
③	**Record**	Displays when ReadMyHeart is in data recall mode.
④	**Send**	Displays when ReadMyHeart is transferring data.
⑤	Total Number/ Data File Number	During power on mode, the number represents the total number of data files recorded. In data recall mode, the number represents the serial number of data file being displayed.
⑥	Battery Condition	indicates the battery is normal. indicates the battery is low.
⑦	**Noise**	**Noise** is displayed after measurement when noisy signals are detected more than 5 times during measurement. PLEASE MEASURE AGAIN. Note: Under above conditions, parameters displayed on LCD may not be accurate but will still be stored in the device.
⑧	HR	Average Heart Rate of 15 seconds. **Flashes** right after measurement when the numbers are out of reference range.
⑨	ST	ST segment. **Flashes** right after measurement when the numbers are out of reference range.
⑩	QRS	QRS interval. **Flashes** right after measurement when the numbers are out of reference range.
⑪	Date/Time	Month/Day/Hour/Minute

2.4 Product Specifications

Input impedance	> 10 M - Ohm
Input dynamic range	+/- 2 mV
Bandwidth	0.15 – 40 Hz
CMRR (Common Mode Rejection Ration)	> 60 db
A/D conversion	12 bit
Sampling frequency	250 samples/sec
Measurement Time	~25 seconds (First 10 seconds is to search for signals)
Display	LCD display panel
Input	Dry conduction electrodes and/or external auxiliary electrodes
Output	USB interface
Power Supply	1.5V (AAA) X 2
Size	12 × 8 × 2 cm
Weight	134 g (Not including batteries)
Environmental Conditions:	
Storage temperature	-4°F ~122°F (-20°C~ 50°C)
Operating temperature	50°F ~104°F (10°C ~ 40°C)
Humidity	25% ~ 95%
Measurement Range:	
Average heart rate	45 to 180 bpm
ST segment	-3 to +3 mm
QRS interval	< 0.20 sec

ReadMyHeart SOFTWARE

3.1 System Requirements

Operating System: Windows 98/98SE/2000/XP/Vista

Hardware Requirements:

- CPU: Pentium III and above
- Memory: 100MB and above
- Hard Disk capacity: 100MB and above
- Data transmission media: Universal Serial Bus (USB)
- Screen resolution: 1024 x 768

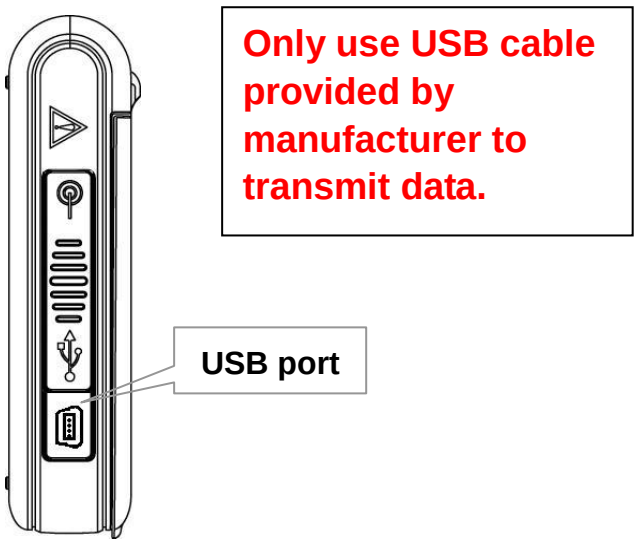
3.2 Installation

Figure 3. ReadMyHeart Software Main Page

Insert ReadMyHeart software CD into the CD-ROM. Select “Software Installation” from the main page and setup will run automatically. If auto-installation does not start, double click on the “autorun.exe” application file in the CD to install manually. Follow the Setup Wizard instruction on the screen.

3.3 Transmit Data

All data files recorded in ReadMyHeart can be transferred to PC for analysis through the USB port on the left side of ReadMyHeart shown in below. Slide the socket cover to expose the USB socket.



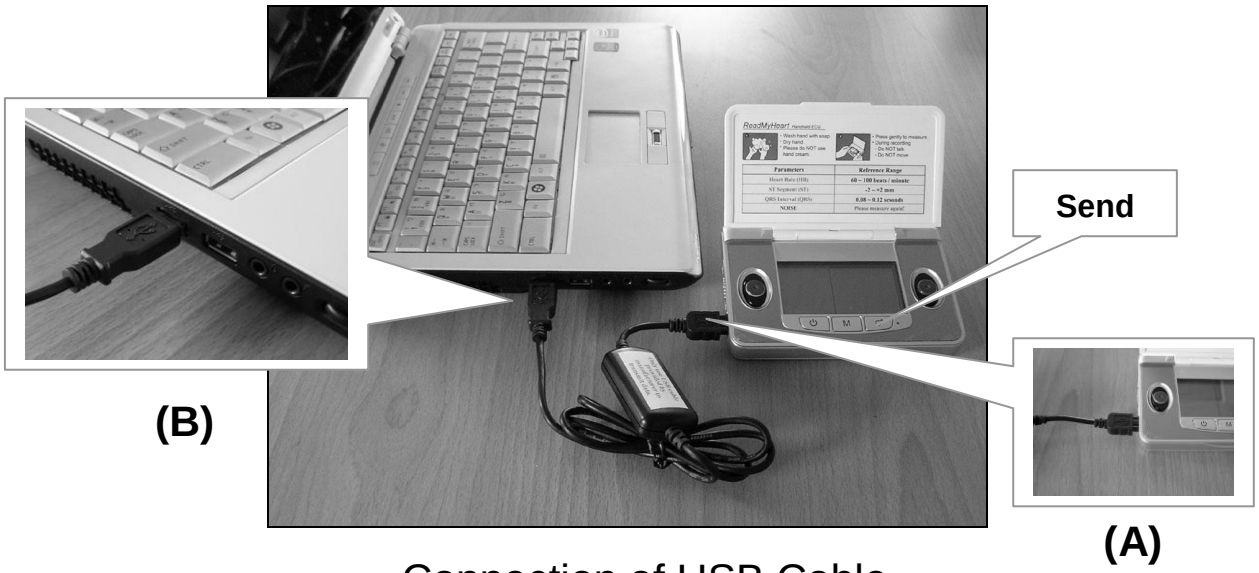
ReadMyHeart USB port

Steps for file transfer. Please follow the following steps:

1. Start the ReadMyHeart software by selecting DailyCare Biomedical Inc → ReadMyHeart from the File Menu or by clicking on the on your desktop.
2. A “Disconnected” status will be shown initially on the bottom left of the main menu.

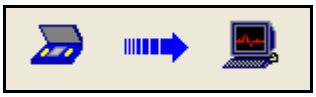
   Connect one end of the USB cable (small) to the USB socket on the hardware first (A). Then connect the other end of the

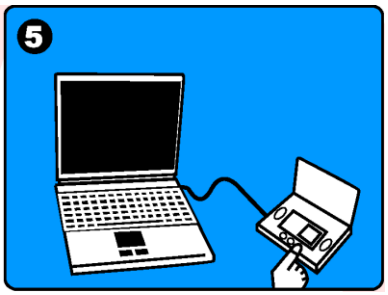
USB cable to the USB port on the computer (B).



Connection of USB Cable

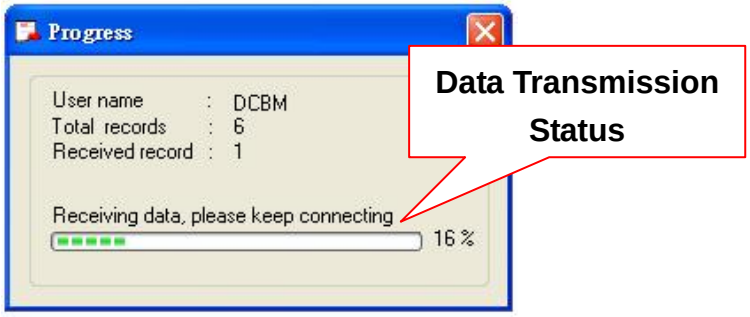
3. When the USB connection detected, it will be indicated on the bottom left corner of the software screen.





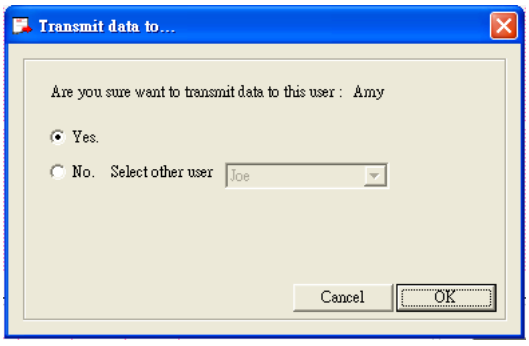
Only use USB cable provided by manufacturer to transmit data.

4. Press ⏻ on ReadMyHeart and **Send** will appear on the LCD display, indicating a transfer of the data files to the PC. The number below **Send** is the serial number of the data files currently downloading to the PC. A transmission window will appear on the PC to show data transmission in progress as shown below.



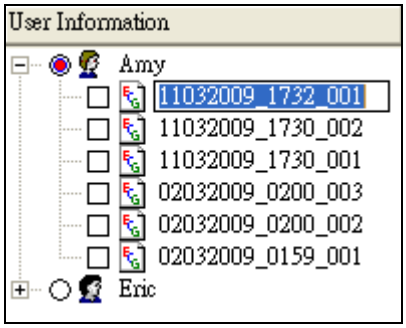
Data Transmission Progress Window

Note: Please confirm/select the right user before the transmitted data save to the PC. The user confirm window shown as below.



Note: After data files have been successfully transferred to the PC and when you start your next measurement, **ReadMyHeart hardware will erase its memory automatically.**

Note: The default file name is the time-stamp of the reading. By clicking the selected file name, the user can change the name.



Note: If **Send** flashes after pressing or during file transfer, it means the connection between ReadMyHeart and the PC has failed. Please close and then re-start the software again, and/or reconnect the USB cable.

3.4 Software Interface

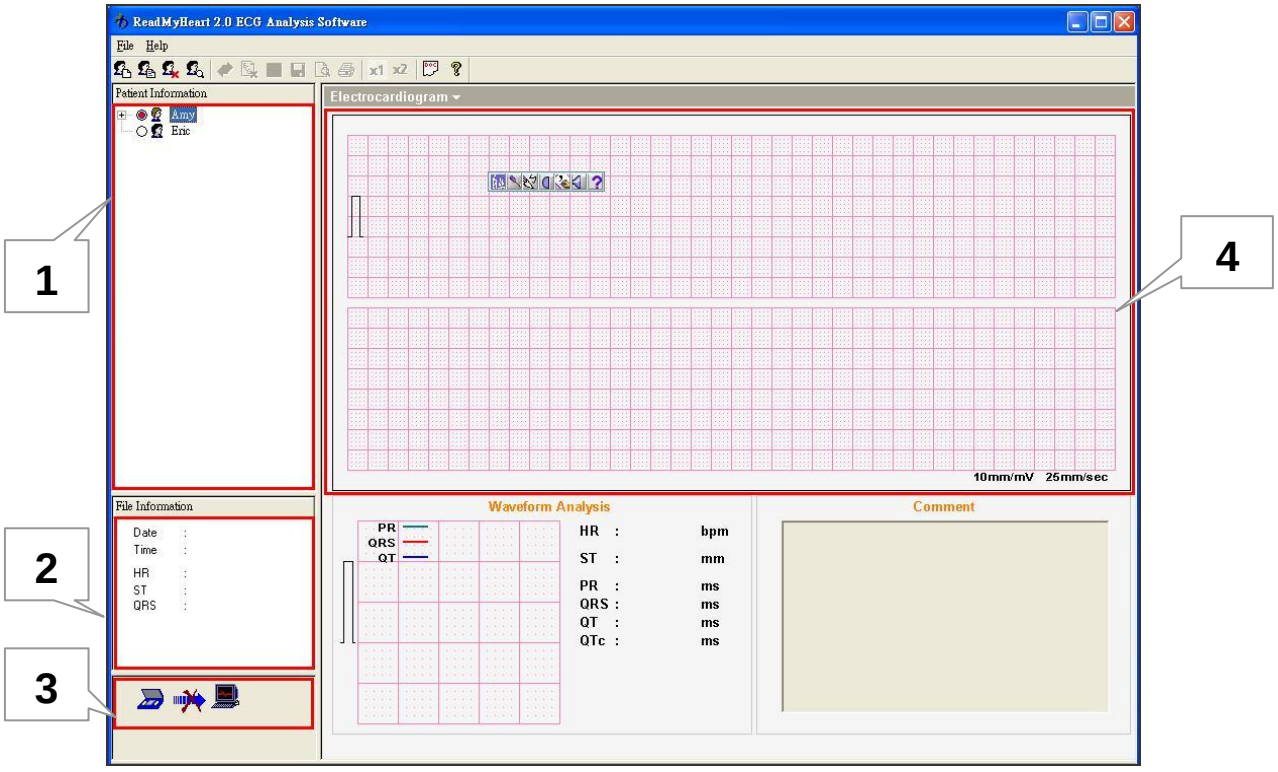


Figure 4. ReadMyHeart Software and Database Interface Details

ReadMyHeart has a simple analysis interface as shown in Figure 4. This analysis and database management system is divided into four main parts:

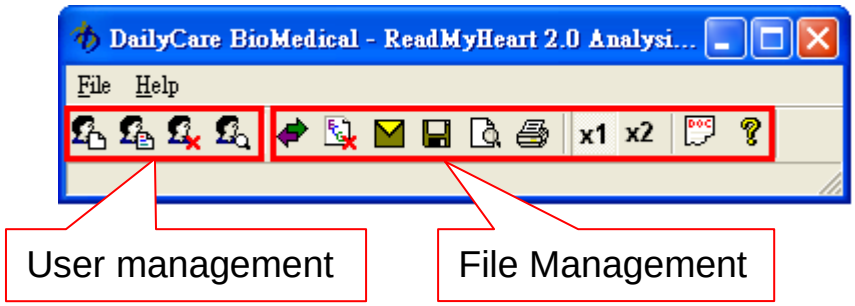
(1) User and file management;

(2) Average ECG parameters display and remarks;

(3) Connection status of ReadMyHeart to PC;

(4) ECG waveform diaplay (Maximum of 15 seconds).

3.5 User Management



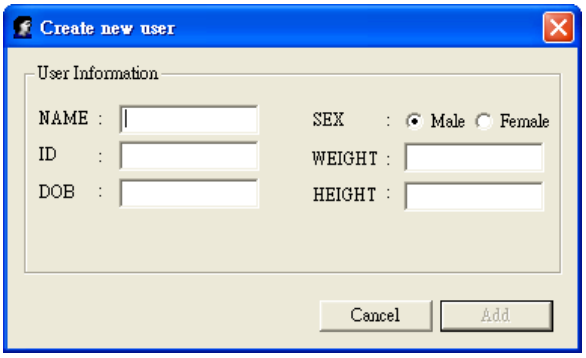
Function Keys	Description
	Add a new user
	Display and change user's information
	Delete selected user
	Search for user
	Move ECG file to other user folder
	Delete selected file

	Email ECG data
	Save ECG waveform as graphic file
	Preview ECG report for printing
	Print ECG report
x1 x2	View between 10mm/mV or 20mm/mV
	Set report's header

Detailed descriptions of Function Keys are as follows:

3.5.1 Add a New User

1. To add a new user, click on function key. The "Create new user" window will appear as shown below.



2. Enter user information such as name, sex, ID, weight, date of birth (DOB) and height.

3. Click on Add and a new user will be added to the user information list. Name of user must be keyed. Otherwise, a

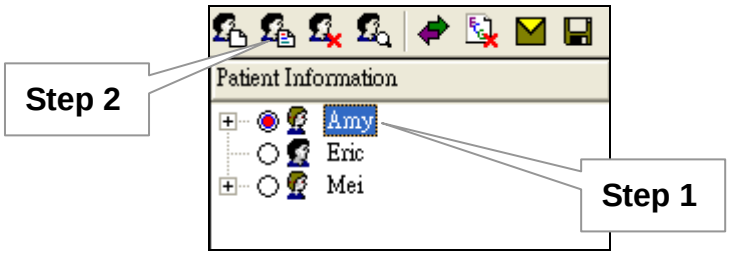
warning window will appear.

4. Repeat step 1 and 2 to add more new users.

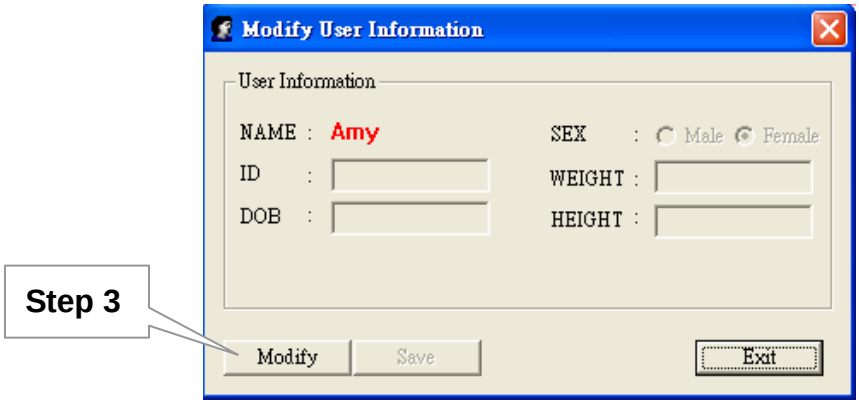
5. Click on [X] to close the user management window.

3.5.2 Display or Change User's Information

1. Select a file/user first.



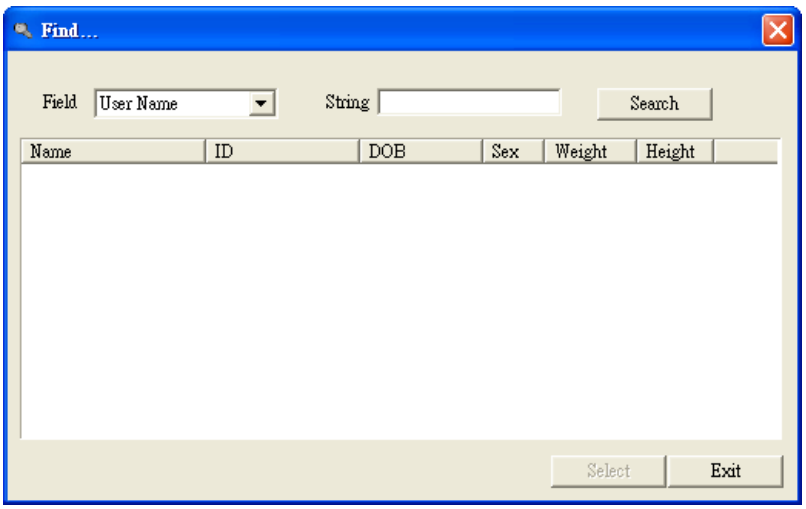
2. Select function key. The user's information will appear as shown below.



You can modify the values on the table after click [Modify]. Then click [Save], all the modified values will be saved automatically. Click [Exit], The values will NOT be changed.

3.5.3 Search for User

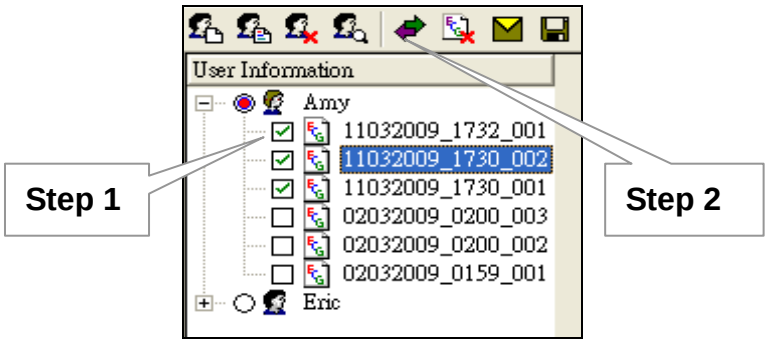
1. Select function key. A window will appear. You can search by “User Name” or by “ID”. Please type in your search characters in the String field.



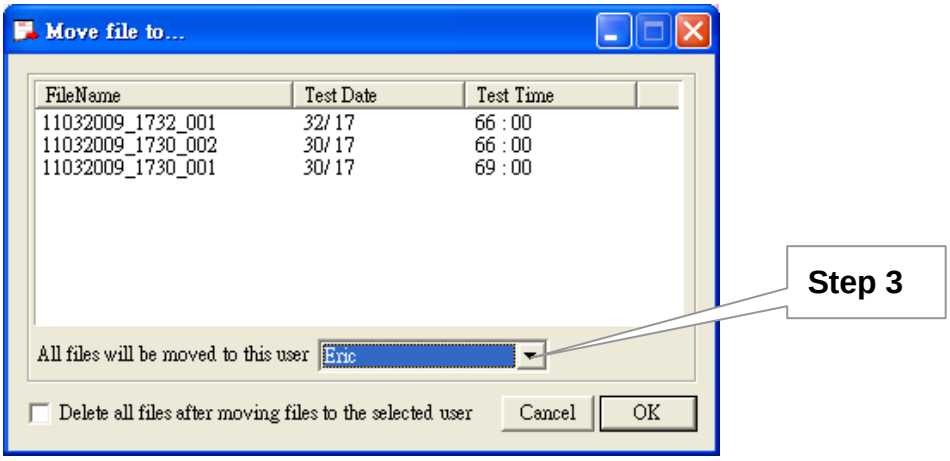
2. Select Find to start finding. If the user is found, the name will be highlighted.

3.5.4 Move ECG file to other User folder

1. Select the files first (Multiple files can be selected).

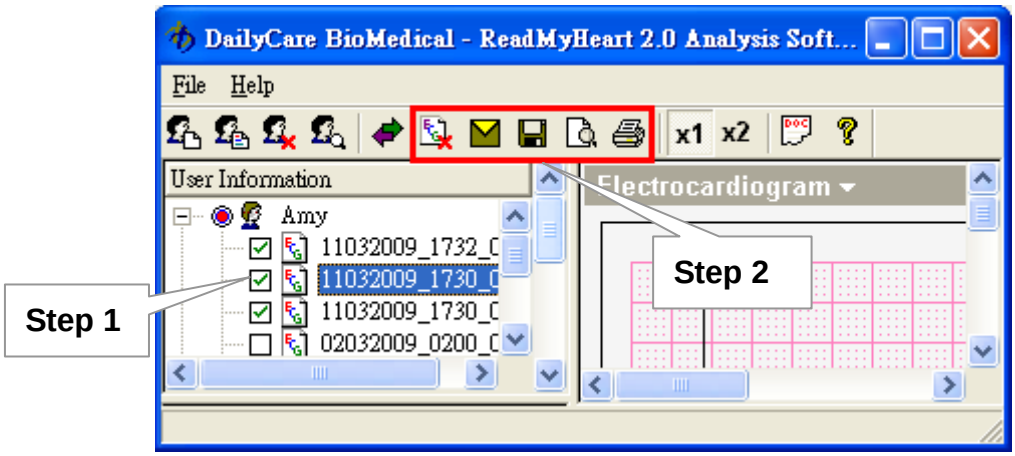


2. Click function key. A window will appear. You can move the selected ECG file to other user.



3.5.5 Delete, E-mail, Save, Preview and Print a File

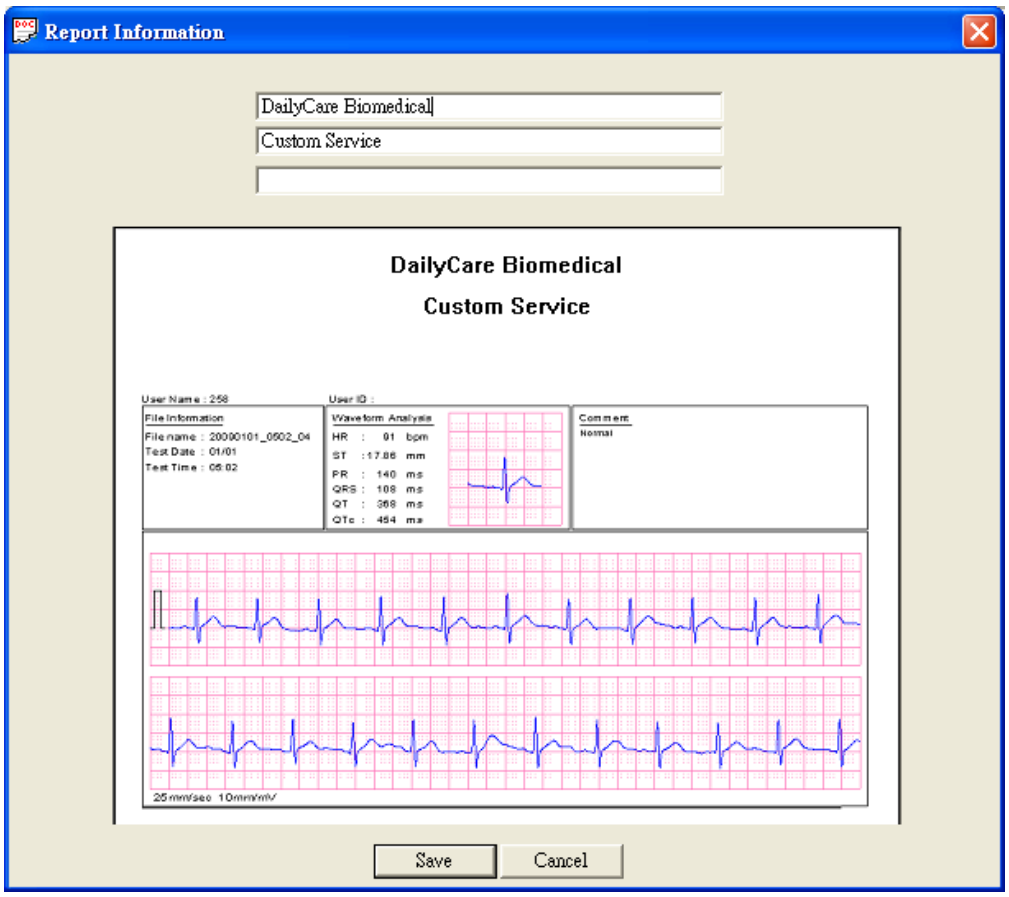
1. .Select the files first (Multiple files can be selected).



2. Click delete, email, save, preview, or print function.

3.5.6 Set Report Header

1. Select function key. The “Report information” window will appear as shown below.



2. Enter header information. Click on Save, and the header information will show on the top of the ECG report.

3.5.7 Review ECG Trace and Parameters

1. Select a user and click on a file.

2. A 15 seconds ECG trace will be shown on the right side of the screen in quadrant 1. (Q1)

NOTE: If you stop ECG measurement in less than 25 seconds, you will not have the full 15 seconds ECG trace.

3. The average ECG parameters (HR, PR, QRS, QT, QTc, ST) will be displayed in quadrant 2. (Q2)

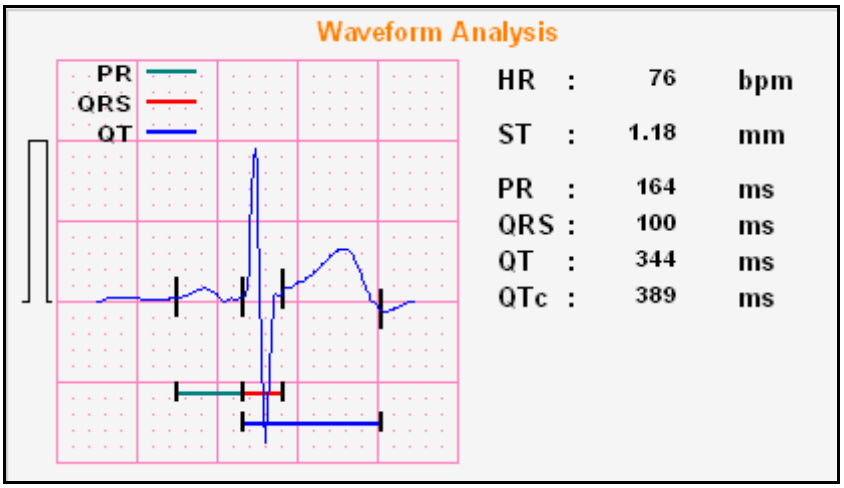
4. You can also select a particular section of the ECG trace, by

clicking left click once to start and left click again to end the section in Q1. The selected part of the trace will turn blue. The average ECG parameters will be displayed in Q2 accordingly.

3.5.8 Redefine ECG Parameters

This section is highly recommended for doctors only. The power of the device lies in the algorithm which identifies and defines P, Q, R, S and T wave intervals to generate the parameters observed on the file. The algorithm is highly precise and accurate which is observed in a correlation study with standard ECG device.

In order to present a flexible format, the software is developed with the ability to redefine the waves. This should only be done by a medical professional who has great experience with ECG analysis and interpretation. Therefore, users are strongly advised against performing the function in this section unless under the guidance of a medical professional.



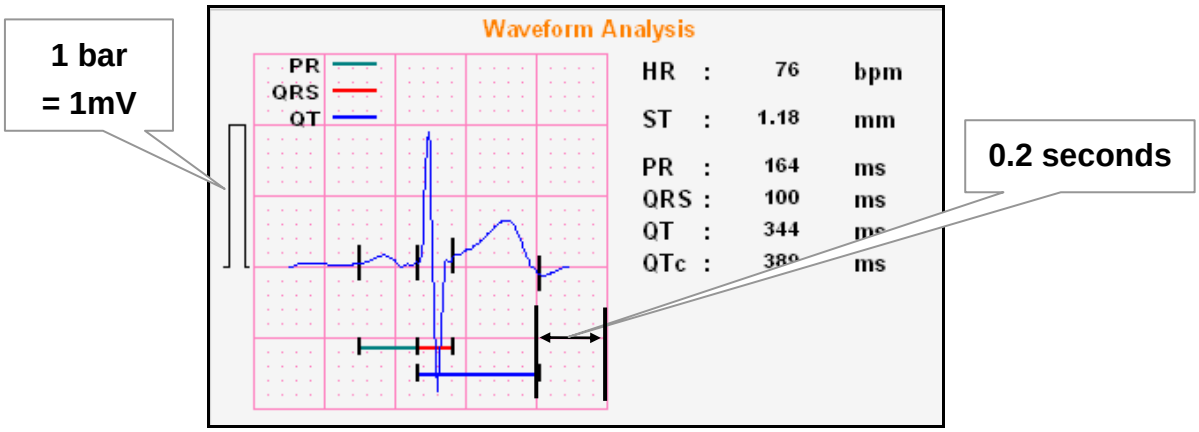
Steps to redefine ECG waves:

1. ECG parameters will be calculated automatically.
2. If you click on the vertical bars on the ECG waveform, it will change to a red bar. Use the left and right arrow key to move it. The software will automatically recalculate the parameters.
3. Left click on the ECG waveform after you have finish adjusting the bar.

3.5.9 Reading the Graph

The Y-axis represents voltage in mV. The bar indicated below represents 1millivolt (mV). This denotes the electrical strength of the signal. Therefore, each big square represent 0.5 mV and each small square represent 0.1mV.

The X-axis represents time in seconds. Each big square represents 0.2 seconds. Therefore, each small square represents 0.04 seconds.



ECG graph

3.5.10 ECG Waves and Parameters

The following is a summary of the ECG wave morphologies and parameters that users can use as a guide to interpret their ECG recordings. For more technical information, please refer to the reference section.

- **P wave:** The P wave results from atria contraction. P wave is generally about 1 box wide or 1 box tall. P wave that exceeds these might indicate atria hypertrophy, i.e., enlargement.
- **PR Interval**: The PR interval is measured from the start of the P wave to the start of Q wave. It represents the duration of **atria depolarization**. Normal duration is from

0.12 to 0.20 seconds. If the PR interval is greater than 0.20 seconds, then an AV block might be present.

- **QRS Duration**: The QRS duration is measured from the start of Q wave to the end of S wave. It represents the duration of **ventricle depolarization**. Normal duration is from **0.08 ~ 0.12 seconds**. If duration is longer, it might indicate presence of bundle branch blocks.
- **QT/QT_c**: The QT/QT_c is measured from the start of the Q wave to the end of T wave. QT interval represents the duration of **activation and recovery of the ventricular muscle**. This duration varies inversely with the heart rate. The normal QT_c is approximately **0.41** seconds, it is corrected with the heart rate with the following formula to get QT_C: $QT_C = QT / sqrt (RR)$

  RR is interval between R to R peak.
- **ST Segment**: The ST segment is measured from end of S wave, J point, to the start of T wave. This segment is important in identifying pathology such as myocardial infarction (elevation) and ischemia (depression).

To learn more about the analysis of ECG parameters, please refer to the list of references provided in the Reference Section.

FREQUENTLY ASKED QUESTIONS

Q1: What is ReadMyHeart?

A1: ReadMyHeart is a personalized, home care heart monitoring device. The main function of ReadMyHeart is to record ECG tracings anywhere and anytime. Using uniquely designed dry electrodes, users only need to place both thumbs on the electrodes, and their ECG will be recorded. The parameters measured will be displayed on the LCD screen. Together with the software, users can transfer data files to PC for the management of data.

Q2: Why does **"Noise"** appear during measurement?

A2: ReadMyHeart measures the electrical activities emitted by the heart. The "Noise" is the interference with the recording of these signals due to poor contact between the thumbs and the electrodes, excessive movement of the body, and other the environment, etc. When using ReadMyHeart, it is recommended that users take a stable sitting position, with their feet insulated from the ground. Please measure again when "Noise" appears on LCD screen after the device finishes recording. For detailed operating procedure, please refer to P.9 of the User's Manual.

Q3: What are some of the factors that may affect the measurement by ReadMyHeart?

A3: Besides the factors mentioned in Q2, the followings are some of the factors that may also affect measurements:

1. Thumbs may be greasy, which may affect the transmission of signals. Please use clean water to clean thumbs.

2. Thumbs may be too dry. DO NOT use cream. Please use external auxiliary electrode cable & sticky electrode pad.

3. Contact pressure between the thumbs and the electrodes may be too strong. Please place thumbs on the electrodes gently.

Even when users have followed the regular procedure described in the User's Manual to operate ReadMyHeart, the user may still experience a weak signal. Please contact the distributor, retailer, or visit DailyCare BioMedical's website: www.dcbiomed.com.

Q4:	How do you use the optional auxiliary electrodes?
A4:	The optional auxiliary electrodes are for users who cannot hold ReadMyHeart steadily without shaking, or users whose thumbs are too dry. For detailed instructions, please follow the steps described in P.10 of the User's Manual. Please note that the electrode pads are NOT included. Please buy the electrode pads from a medical device store.
Q5:	Can ReadMyHeart be stopped or powered off in the middle of the measurement?
A5:	During the 25 seconds measurement, ReadMyHeart cannot be stopped or powered off.
Q6:	Will static electricity affect the measurement of ReadMyHeart?
A6:	ReadMyHeart is CE certified and has passed electromagnetic interference and compatibility tests. Under normal circumstances, static electricity will not affect the operation of ReadMyHeart.
Q7:	How do you manage ECG signals if multiple people use a single ReadMyHeart device?
A7:	Data cannot be managed on the ReadMyHeart device directly. If there is more than one user, please use the software provided for data management. For detailed information, please refer to the User's Manual.
Q8:	Why does the temperature of ReadMyHeart rise after the batteries are inserted?
A8:	The rise in temperature is caused by the improper direction of the poles of the batteries when inserted. Please remove the batteries quickly and then reinsert the batteries correctly. Please allow the ReadMyHeart to drop to a normal operating temperature before making any measurements.
Q9:	Can the parameters measured by ReadMyHeart be used for clinical diagnosis?
A9:	The ECG tracings recorded by ReadMyHeart is not for clinical diagnostic purposes. It is only to be used for physician's reference, and to be used for personal home care health management.

Q10: Why does the data recorded in the ReadMyHeart disappear after batteries are replaced?

A10: Data will remain in the memory for approximately 2 minutes only during battery replacement. Thus, please replace batteries as quickly as possible to preserve data.

Q11: Why does the transferred files to PC and the number of times measured on ReadMyHeart not match?

A11: ReadMyHeart can store up to 30 data files in its memory only. Please remember to transfer data files to the PC, or erase the memory, if you want to make the next measurement. This is to make sure that you record and transfer all important ECG data to the PC for health management.

Q12: How do you transfer ReadMyHeart's ECG data files by internet?

A12: User needs to SAVE the data files first using ReadMyHeart's exclusive software before sending the files by e-mail. For the detailed procedures, please refer to the software instruction manual (P.23).

Q13: How do you maintain ReadMyHeart?

A13: When the dry conduction electrodes on ReadMyHeart are used regularly, grease and dirt may accumulate, which may affect the recording of signal. Please use a clean wiping cloth to remove grease and dirt. Please DO NOT use any cleaning solutions or organic solvents to prevent damaging the device.

Q14: Can ReadMyHeart use other external power supply?

A14: No. ReadMyHeart is to be operated by two replaceable 1.5V (AAA) alkaline batteries. Please do not use other external power supply which may be hazardous and may damage the device.

Q15: Can ReadMyHeart use accessories other than the ones provided in the standard package?

A15: All standard package accessories meet special specifications of medical device regulations. Please DO NOT use any other accessories other than the ones provided in the standard package to avoid hazards and subsequent damages to the device and to avoid hazards.

Q16:	What to do if the parameters measured by ReadMyHeart do not correspond with the user's condition?
A16:	In case of an emergency physical condition, users should contact emergency services immediately, or go report immediately to the hospital. If the measured parameters do not correspond with user's condition, please make sure all standard operating procedures are followed. If not, please contact a physician for further check up.
Q17:	Can any other fingers be used beside the thumbs for measurement of ECG?
A17:	You may use other fingers other than the thumbs for measurment using ReadMyHeart. Please make sure you place the fingers gently on the electrodes and Do NOT move and talk during measurement. You may choose to use external electrode cable and ECG pads for better ECG trace measurement.
Q18:	Can ReadMyHeart be used while the user is standing up, sitting down, or lying down? Will the measurements make any difference?
A18:	Different body positions may affect the cardiac signals slightly. However, by following the standard operating procedure closely, ReadMyHeart is able to record ECG signals correctly.
Q19:	After exercising, can ECG be measured using ReadMyHeart? Wiill the measurement be correct?
A19:	Yes, ECG can be recorded after exercise. During measurement, please remain in a stable position to avoid noise interference.
Q20:	Can ReadMyHeart be used during commuting?
A20:	During commuting, if user is able to keep a stable position, ReadMyHeart can be used to measure ECG. Usage of ReadMyHeart is not recommended during the operation of any vehicle.
Q21:	Can conducting gel or other fluids be used when using ReadMyHeart?
A21:	ReadMyHeart is designed to be operated without any conducting gel or other fluids. Please do not apply any conducting gel or other fluids to avoid damaging the thumb electrodes and the device.

GLOSSARY

Aorta

The main trunk of the systemic arteries, carrying blood from the left side of the heart to the arteries of all limbs and organs except the lungs.

Arrhythmia

Irregularity in the force or rhythm of the heart beat.

Atrioventricular (AV) Node

A small mass of specialized cardiac muscle fibers, located in the wall of the right atrium of the heart, that receives heartbeat impulses from the sinoatrial node and directs them to the walls of the ventricles.

Bundle of His

A slender bundle of modified cardiac muscle that passes from the atrioventricular node in the right atrium to the right and left ventricles by way of the septum and that maintains the normal sequence of the heartbeat by conducting the wave of excitation from the right atrium to the ventricles called also *atrioventricular bundle, His bundle*.

Electrocardiogram

The curve traced by an electrocardiograph.

Electrocardiograph

An instrument used in the detection of heart abnormalities. It measures electrical potentials on the body surface and generates a record of the electrical currents associated with heart muscle activity.

Heart Rate (HR)

The number of heartbeat per unit time, usually in minutes.

Hypertrophy

A non-tumorous enlargement of an organ or a tissue as a result of an increase in the size rather than number of constituent cells.

Inferior Vena Cava

Large vein formed by the union of the two common iliac veins that receives

blood from the lower limbs and the pelvic and abdominal viscera and empties into the right atrium of the heart.

Left Atrium

Top left chamber of the heart.

Left Ventricle

Bottom left chamber of the heart.

mm

One mm is one small square on the electrocardiograph.

Myocardial Infarction

Formation of an area of tissue that undergo necrosis as a result of obstruction of local blood supply, as by a thrombus or embolus.

P Wave

Atrial Depolarization (contraction). Normal duration is 0.06 - 0.11 second.

Parameters

A distinguishing characteristic or feature.

PR Interval

Atrial and AV node depolarization. Regular duration is 0.12 - 0.20 seconds.

QRS Interval

Ventricular depolarization. Regular duration is no longer than 0.1 second.

QT Interval

Ventricular refractory time. Duration varies according to rate, age and sex.

Right Atrium

Top right chamber of the heart.

Right Ventricle

Bottom right chamber of the heart.

Right/Left Bundle Branch

Either of the parts of the bundle of His passing respectively to the right and left ventricles.

Sinoatrial (SA) Node

A small mass of specialized cardiac muscle fibers located in the posterior wall of the right atrium of the heart that acts as a pacemaker by generating at regular intervals the electric impulses of the heartbeat.

ST Segment

ST segment represents the period from the end of ventricular depolarization to the beginning of ventricular repolarization.

Superior Vena Cava

A large vein formed by the union of the two brachiocephalic veins and the azygos vein that receives blood from the head, neck, upper limbs, and chest, and empties into the right atrium of the heart.

T Wave

Ventricular Repolarization. Usually 0.5mV or less in Lead I, II and III.

REFERENCES

1. American Heart Association www.americanheart.org
2. National Heart, Lung and Blood Institute www.nhlbi.nih.gov
3. ECG Library www.ecglibrary.com
4. eMedicine www.emedicine.com
5. HeartCenterOnline www.heartcenteronline.com

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